(3) Fees are due at the time a request for review is made. IRB determinations will not be granted until payment is received by the Department.

(4) Fees are nonrefundable, except if a fee is paid when none is due. Specific instructions on how to pay the fee are available at the website indicated in subsection (1).

(5) Fees do not apply to Department of Health employees, including contracted employees, or investigators conducting research involving human subjects at the request of the Department under a contract, memorandum of understanding, or similar agreement except when the sponsor makes an allowance for fees in the research contract. Fees are waived for any student who is a candidate for a degree at a university located in Florida.

Specific Authority 381.86 FS. Law Implemented 381.86(5) FS. History–New 9-2-08.

Section II
Proposed Rules

DEPARTMENT OF STATE

Division of Cultural Affairs

RULE NOS.:	RULE TITLES:
1T-1.001	Division of Cultural Affairs
1T-1.031	Historical Museum Grants Application Requirements
1T-1.032	History Museums Application Review and Grant Administration

PURPOSE AND EFFECT: This amendment transfers the Historical Museums Grants-in-Aid Program from the management of the Division of Historical Resources to the Division of Cultural Affairs; it incorporates minor statutory changes to the program that became effective July 1, 2008 (as authorized by Section 265.708, Florida Statutes); and it incorporates recommendations made by the Historical Museums Task Force. In regard to the Cultural Support Grants Program, this amendment deletes the minimum funding amount of $2,500. This amendment also deletes the Indemnity Grant Program (because it was repealed by the 2005 Legislature); this amendment establishes a funding amount for applicants for the Youth and Children's Museums Program who request over $50,000; and this amendment makes other changes affecting all grant programs of the Division as more fully described in the Summary below.

SUMMARY: This amendment incorporates the recommendations of The Historical Museums Taskforce in that it creates a two (2) year funding period, rather than annual one; it provides three (3) levels of funding catagories, rather than two (2) for the General Program Support category; it provides for alternate years in which museums that request certain levels of funding will compete with each other for funding. This amendment also establishes new eligibility criteria for the Historical Museum Grants-in-Aid Program and clarifies the eligibility criteria for multidisciplinary museums. This amendment deletes the Indemnity Grant Program because the program statutes were repealed (see former Sections 265.51 – 265.55, Florida Statutes). This amendment allows grantees who request over $50,000 for the Youth and Children's Museums Grant Program to request up to 10% of their last completed fiscal year's revenue. In regard to all grant programs of the Division, this amendment prohibits funding for general "operating expenses" such as utilities, fixtures, bank fees, property taxes, etc., and requires that grant deadlines be posted on the Division of Cultural Affairs' website, rather than in the Division's online newsletter.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: There are no regulatory costs associated with this proposed rule. This amendment does not have an impact on small business.

Any person who wishes to provide information regarding the statement of regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 255.043(4), 265.284(5)(d), 265.285(1)(c), 265.286(1), (4), (6), 265.2861(2)(b), (f), 265.2865(6), 265.51, 265.605(1), 265.608(1), 265.609(1), (4), 265.701(5), 265.702(8), 265.708(3) FS.

LAW IMPLEMENTED: 215.97, 255.043, 265.284, 265.285, 265.286, 265.2861, 265.2865, 265.601-.603, 265.605-.607, 265.608, 265.609, 265.701, 265.702, 286.011, 286.012, 286.25, 288.0656, 288.06561, 265.708 (formerly 267.0619) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: Wednesday, January 24, 2009, 9:00 a.m.

PLACE: Division of Cultural Affairs, 500 South Bronough Street, R. A. Gray Building, 3rd Floor, Tallahassee, Florida

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 72 hours before the workshop/meeting by contacting: (850)245-6356 or Text Telephone 711. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Scott Moore or Sarah Stage, (850)245-6470

THE FULL TEXT OF THE PROPOSED RULES IS:

1T-1.001 Division of Cultural Affairs.

The purpose of the rule is to establish administrative procedures for all Division of Cultural Affairs (Division) activities.

(1) through (2)(b) No change.

~~(c) Florida Art and Artifacts Indemnity Program. This section provides the procedures for issuing indemnity agreements and processing claims under the Florida Art and Artifacts Indemnity Program. The Florida Art and Artifacts Indemnity Program Guidelines (CA1E017, eff. 2/96) and the Application for Indemnification Under the Arts Indemnity Act (Form CA1E024, eff. 2/96) contain the procedures for accepting and reviewing applications.~~

(3) Grant Application Procedures. The Division shall be responsible for the administration of all grant applications, procedures, and awards, as recommended by the Council. Applicants shall meet all program deadlines as published ~~in the Division's newsletter and posted~~ on the Division's website at www.florida-arts.org and through the Division's online system at http://culturegrants-fl.org; the posted deadlines will appear at least 90 days in advance of the deadline. Deadline dates are also available by calling the Division. Review panel and committee meetings shall be noticed in the Florida Administrative Weekly, on the Division's website, and through the Division's online system. Review panel meetings shall be conducted in accordance with procedures outlined in this rule and in Sections 112.313, 112.3143, 120.525, 286.012, and 265.285, F.S. During the scheduled panel meetings, applications from state-supported institutions will be considered separately from those of private institutions or individuals. All grant awards shall be subject to final approval by the Secretary of State.

(4) through (5)(b) No change.

(c) Submit a completed and signed application. The application form (CA2E009, eff. 2/09) is incorporated by reference and available through the Division's online application system at http://culturegrants-fl.org (unless specifically directed to do otherwise for the grant deadline for the State Touring Program~~, the Cultural Facilities Program, and the Regional Cultural Facilities Program~~) for each program to which application is made on or before the announced deadline for that program. A completed application shall include the following information submitted through the Division's online system: general identification and contact information, operating budget(s), proposal budget, proposal budget detail, proposal description including goals, objectives, activities and evaluation outline, and program narrative responses. Instructions for submitting support documents will also be available through the online system.

(d) Have satisfied the administrative requirements of previous grants received from the Department ~~Division~~ of State;

(e) through 3. No change.

4. State grant funds cannot be used to pay for operating expenses, such as utilities, phone, fixtures, bank fees, maintenance, general supplies, rent, mortgage payments and property taxes. However, these costs may be used as match or in-kind.

5.~~4.~~ REDI Waiver. Cash matching requirements will be waived for applicants that are REDI qualified in accordance with Sections 288.0656 and 288.06561, F.S. Such waivers are only available for Cultural Support Specific Project, Quarterly Assistance, Arts in Education, Culture Builds Florida, Historical Museums Grants-In-Aid Public Educational Exhibits, and Challenge Programs. To obtain a cash match waiver, the applicant must submit, with its application, a letter from the local county government that acknowledges the grant application and requests the waiver. REDI-qualified counties with approved waivers may use up to 100% in-kind match, which must be shown in the proposal budget. A list of REDI counties and communities is reviewed and updated annually, and is available on the Division's website.

6.~~5.~~ Grants awarded in the Challenge Grant Program, the Underserved Arts Communities Assistance Program, and the State Touring Program have match requirements specific to those programs.

(f) through (7)(a)1. No change.

a. Cultural Organizations. Revenues from the organization's last completed fiscal year must be greater than or equal to $25,000. Organizations may request up to 10% of their last completed fiscal year revenue, not to exceed $100,000. ~~Completed fiscal year revenue figures are subject to audit verification by the Division.~~ Youth and Children's Museums as defined in Section 265.609, F.S., may request up to 20% of their last completed fiscal year revenue, not to exceed $50,000. Youth and Children's Museums applicants that request more than $50,000 may request up to 10% of their last completed fiscal year's revenue. Organizations requesting more than $50,000 must have no less than three years of continuous programming history and at least one paid full-time employee.

b. through 2.b. No change.

c. Organizations can only receive one General Program Support grant from the ~~Division of Cultural Affairs and any other division within the~~ Department of State in the same fiscal year. This policy is effective as of July 1, 2008 for Cultural Organizations and July 1, 2010 for Cultural Institutions. The only exception to this limitation is for a multidiscipinary museum, which is defined as a museum that addresses two or more disciplines to a significant extent: for example, a museum that interprets both art and history or both history and science. Multidisciplinary museums will be permitted to receive a total of two General Program Support museum category grants from any ~~other~~ division within the Department of State. A discipline-specific operating budget must be used for each application; multidisciplinary museums cannot use the same

operating budget for both applications. Multidisciplinary museums that submit two General Program Support applications to the Cultural Support Grants Program may request a maximum of $100,000 in the Cultural Organizations category and a maximum of $350,000 in the Cultural Institutions category.

3. No change.

(b) No change.

1. An average panel score of at least 75 points out of a maximum possible 100 points must be earned to be considered for funding for Specific Project applications. The panel is not required to fund all Specific Project applications that receive a minimum average score of 75 points. An average panel score of 80 points out of a maximum possible 100 points must be earned to receive funding for Cultural Organizations applications; and 85 points out of a maximum possible 100 points must be earned to receive funding for Cultural Institutions applications. General Program Support award amounts recommended to the Council will be determined through the use of a funding method for all applications achieving the minimum eligible category-specific score. ~~All General Program Support applications earning an eligible category-specific average will receive funding under the funding method of not less than $2,500.~~ Based on their review, the panel makes funding recommendations for Specific Project grant awards to the Council. In determining which applications to fund, the panel will consider only applications that have achieved the required minimum average score of 75 ~~and other criteria which include the overall group of eligible Specific Project applications, the relative merits of each proposal as demonstrated through scores based on the program review criteria, the anticipated funds available for the program, the perceived needs of the artistic or cultural discipline, the constituency served, and how well the proposed project fulfils the mission of the Cultural Support Grants program~~. ~~In determining award amounts for those proposals recommended for funding, the panel may not recommend funding of less than $2,500.~~

2. through (18)(l) No change.

(m) Reporting. For all programs, unless otherwise specified, the grantee shall file a final report no more than 30 days following the project ending date. Interim reports will be required for grants with ending dates after June 30. These interim reports shall contain program financial and statistical results as of June and must be submitted no later than July 30. A final report and a State Grant Funds Expenditure Log (CA2E119, eff. 2/09) incorporated by reference and available on the Division's website at www.florida-arts.org that includes check number, amount of check, date of check, name of payee, and a description of the expenditure will also be required 30 days after the project ending date. Requests for report due date extensions must be submitted in writing prior to the original due date. Unless otherwise specified, for all grant reporting, grantees must use the Grant Report Form (CA2E004, eff. 10/98) incorporated by reference and available on the Division's website at www.florida-arts.org.

(n) through (20) No change.

Specific Authority 255.043(4), 265.284(5)(d), 265.285(1)(c), 265.286(1), (4), (6), 265.2861(2)(b), (f), 265.2865(6), 265.51, 265.605(1), 265.608(1), 265.609(1), (4), 265.701(5), 265.702(8) FS. Law Implemented 215.97, 255.043, 265.284, 265.285, 265.286, 265.2861, 265.2865, 265.601-.603, 265.605-.607, 265.608, 265.609, 265.701, 265.702, 286.011, 286.012, 286.25, 288.0656, 288.06561 FS. History–New 11-23-82, Formerly 1T-1.01, Amended 10-1-96, 10-31-96, 2-2-97, 6-2-97, 7-17-97, 9-10-97, 1-4-98, 7-26-98, 8-2-98, 10-5-98, 10-25-98, 8-17-99, 8-1-02, 12-29-02, 10-14-03(17), 10-14-03(20), 11-16-03, 2-2-05, 5-16-05, 6-21-05, 12-20-05, 5-22-06, 6-5-06, 6-27-06, 8-20-07, 9-16-07, 1-8-08, 7-8-08, 9-8-08, _____.

(Substantial rewording of Rule 1T-1.031 follows. See Florida Administrative Code for present text.)

1T-1.031 Historical Museum Grants Application Requirements.

(1) Historical Museum Grants. This program provides grants that relate to the historical resources of Florida in two categories: General Program Support and Public Educational Exhibits. General Program Support is on a two-year cycle and Public Educational Exhibits are on an annual cycle.

(2) Administrative and Legal Eligibility. An eligible applicant must:

(a) Be a unit of county, municipal, or other local government; or

(b) Be a department or an agency of the state (exception: history museums that are state-operated are not eligible for General Program Support grants); or

(c) Be a public or private nonprofit corporation, a partnership, or other organization. For the purposes of this rule, a nonprofit corporation is one that is tax-exempt as defined in section 501(c)(3) or 501(c)(4) of the Internal Revenue Code of 1954, as amended; and in good standing pursuant to Chapter 617, F.S., known as the Florida Not for Profit Corporations Act.

(d) Have satisfied the administrative requirements of previous grants received from the Department of State.

(e) Not be a for-profit museum.

(3) Eligibility for General Program Support.

(a) In addition to the requirements in subsection (2) of this rule, General Program Support applicants must satisfy the criteria in Section 265.708(2), Florida Statutes.

(b) Applicants may only submit one application to the History Museum Program per grant cycle. Organizations may only receive one General Program Support grant from the Department of State in the same fiscal year. The only exception to this limitation is that multidisciplinary museum applicants may receive a total of 2 General Program Support Grants museum category grants from any division within the

Department of State. A discipline-specific operating budget must be used for each applicant; multidisciplinary museums cannot use the same operating budget for both applications.

(c) Only the portion of the applicant's operating budget that addresses Florida history may be used in the grant budget.

(d) General Program Support applicants are not eligible for Public Educational Exhibits or the Cultural Support Grants Program Specific Projects.

(4) Eligibility for Public Educational Exhibits.

(a) Exhibits must address Florida history.

(b) Applicants may only submit one application to this category.

(c) Educational Exhibit applicants are not eligible for General Program Support.

(5) Application Requirements. Applications shall consist of the following:

(a) A complete and signed Application (CA2E138, eff. 2/09), incorporated by reference and available from the Division, submitted on or before the deadline, which will be posted on the Division's website.

(b) A complete application includes the following:

1. General identification and contact information, operating budget(s), proposal budget, and program narrative responses.

(c) Application Support Material.

1. For nonprofit organizations, a copy of the organization's Letter of Determination documenting nonprofit status as defined by section 501(c)(3) or 501(c)(4) of the *Internal Revenue Code of 1954*.

2. Rural Economic Development Initiative (REDI) Waiver. Only Public Educational Exhibit applicants may request a waiver of the cash matching requirement in accordance with Sections 288.0656 and 288.0651, Florida Statutes, and in doing so, should include a copy of the letter from county government acknowledging the grant and requesting the REDI waiver on behalf of the organization. REDI-qualified counties with approved waivers may use up to 100% in-kind match, which must be shown in the proposal budget. A current list of REDI counties and communities is available on the Division's website. General Program Support applicants are not eligible for a REDI waiver.

(d) Funding Request.

1. Public Educational Exhibit applicants may request up to $35,000.

2. General Program Support applicants may request up to 20% of the museum's operating revenue for the last completed fiscal year, not to exceed $75,000.

(e) Matching Funds.

1. Grants must be matched at a minimum of $1 local for every $1 state.

2. The documented fair market value of donated goods and services may contribute up to 50% of the required match, not to exceed 25% of the total project or general program costs.

3. State-supported institutions may not use state funds from any source as match.

Specific Authority 255.043(4), 265.284(5)(d), 265.285(1)(c), 265.286(1), (4), (6), 265.2861(2)(b), (f), 265.2865(6), 265.51, 265.605(1), 265.608(1), 265.609(1), (4), 265.701(5), 265.702(8) FS. Law Implemented 215.97, 255.043, 265.284, 265.285, 265.286, 265.2861, 265.2865, 265.601-.603, 265.605-.607, 265.608, 265.609, 265.701, 265.702, 286.011, 286.012, 286.25, 288.0656, 288.06561 FS. History–New 11-23-82, Formerly 1T-1.01, Amended 10-1-96, 10-31-96, 2-2-97, 6-2-97, 7-17-97, 9-10-97, 1-4-98, 7-26-98, 8-2-98, 10-5-98, 10-25-98, 8-17-99, 8-1-02, 12-29-02, 10-14-03(17), 10-14-03(20), 11-16-03, 2-2-05, 5-16-05, 6-21-05, 12-20-05, 5-22-06, 6-5-06, 6-27-06, 8-20-07, 9-16-07, 1-8-08, 7-8-08, 9-8-08, Formerly 1A-43.007, Amended _____.

(Substantial rewording of Rule 1T-1.032 follows. See Florida Administrative Code for present text.)

1T-1.032 History Museums Application Review and Grant Administration.

(1) Grant review panels will be established in accordance with subsection 1T-1.001(6), Florida Administrative Code to review and evaluate grant applications using the criteria below.

(2) Panel review criteria. There will be a maximum of 100 points, to be used to evaluate and score applications as follows:

(a) Program Excellence – up to 50 points;

(b) Public Impact – up to 30 points;

(c) Program Management – up to 20 points; and

(3) All grant awards will be formalized through execution of a Grant Award Agreement available from the Division of Cultural Affairs which shall consist of all documents referenced in paragraph 1T-1.001(18)(b), Florida Administrative Code.

(4) Non-allowable grant expenses. Grant funds may not be used to pay the expenses of:

(a) Locating, identifying, evaluating, acquiring, preserving, protecting, restoring, rehabilitating, stabilizing, or excavating an archeological or historic site or a historic building or planning any of those activities; or,

(b) Operating expenses, such as utilities, phone, fixtures, maintenance, general supplies, rent, bank fees, mortgage payments and property taxes. (These costs may be used as match or in-kind.).

(c) Other non-allowable expenses as detailed in paragraph 1T-1.001(18)(i), Florida Administrative Code.

(5) Grant Reporting.

(a) The grant reporting period begins on July 1 and ends on June 30.

(b) If the grant reporting period is extended beyond June 30, an Interim Report is required. Interim Reports are due no later than July 31.

(c) A Final Report is due no later than 30 days following the grant end date.

(d) Interim and Final Reports shall be submitted using the Grant Report Form (CA2E004, eff. 10/98) incorporated by reference and available on the Division's website at www.florida-arts.org.

(e) A State Grant Funds Expenditure Log (CA2E119, eff. 2/09), incorporated by reference and available on the Division of Cultural Affairs website must be submitted with all grant reports.

(6) Grant Revisions. Revisions to grants will be administered in accordance with paragraph 1T-1.001(18)(e), Florida Administrative Code.

Specific Authority 255.043(4), 265.284(5)(d), 265.285(1)(c), 265.286(1), (4), (6), 265.2861(2)(b), (f), 265.2865(6), 265.51, 265.605(1), 265.608(1), 265.609(1), (4), 265.701(5), 265.702(8) FS. Law Implemented 215.97, 255.043, 265.284, 265.285, 265.286, 265.2861, 265.2865, 265.601-.603, 265.605-.607, 265.608, 265.609, 265.701, 265.702, 286.011, 286.012, 286.25, 288.0656, 288.06561 FS. History–New 11-23-82, Formerly 1T-1.01, Amended 10-1-96, 10-31-96, 2-2-97, 6-2-97, 7-17-97, 9-10-97, 1-4-98, 7-26-98, 8-2-98, 10-5-98, 10-25-98, 8-17-99, 8-1-02, 12-29-02, 10-14-03(17), 10-14-03(20), 11-16-03, 2-2-05, 5-16-05, 6-21-05, 12-20-05, 5-22-06, 6-5-06, 6-27-06, 8-20-07, 9-16-07, 1-8-08, 7-8-08, 9-8-08, Formerly 1A-43.009, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: David Moore or Sarah Stage

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Kurt Browning, Secretary of State

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 23, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 14, 2008

DEPARTMENT OF LAW ENFORCEMENT

RULE NO.:	RULE TITLE:
11-1.0041	Confirmation and Delegation of Authority

PURPOSE AND EFFECT: To update the language for rulemaking authority based upon recent statutory changes.

SUMMARY: Specifies that the approval of the Governor and Cabinet acting as the head of the Department is required for rulemaking under Chapter 120, F.S.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 943.03(4) FS.

LAW IMPLEMENTED: 20.05(1)(b), 20.201, 112.061, 120.63(1), 216.345, Chapter 943 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: Wednesday, February 4, 2009, 10:00 a.m.

PLACE: Department of Law Enforcement, 2331 Phillips Road, Tallahassee, Florida 32308

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Fern Rosenwasser at (850)410-7676. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Fern Rosenwasser, Florida Department of Law Enforcement, Office of General Counsel, 2331 Phillips Road, Tallahassee, Florida 32308

THE FULL TEXT OF THE PROPOSED RULE IS:

11-1.0041 Confirmation and Delegation of Authority.

(1) In accordance with paragraph 20.05(1)(b), F.S., the Executive Director and other officials of the Department of Law Enforcement are hereby authorized to perform or exercise the following statutory powers and duties of the Agency, Department, or Department Head:

(a) The Executive Director or, his designee shall:

1. through 11. No change.

12. Act on behalf of the agency in carrying out the provisions of Chapter 120, F.S., provided, however, the Governor and Cabinet shall approve all Department administrative rules and reserve the prerogative to act as hearing officer in Section 120.57, F.S., proceedings involving great public interest or other public agencies. Examples include the following:

a. To initiate rulemaking by publishing a notice of intended action. ~~However, before a notice of intended action is published, the Department must submit the proposed notice including the proposed text to the Governor and each member of the Cabinet. Upon the request of the Governor or any member of the Cabinet, the Department shall submit the proposed rules for action by the Governor and Cabinet at the next available Cabinet meeting. If, after being given 10 working days to review the Department's proposed notice of intended action and rule text, neither the Governor nor any member of the Cabinet notifies the Department of his or her objection to such publication, the Department has authority to proceed to initiate rulemaking pursuant to Section 120.54(3)(a)1., F.S.~~ The power to determine whether proposed

rules should be approved for the filing of a notice of intended action and final adoption is hereby reserved to the Governor and Cabinet acting as the head of the Department.

b. through h. No change.

(b) through (f) No change.

Specific Authority 943.03(4) FS. Law Implemented 20.05(1)(b), 20.201, 112.061, 120.63(1), 216.345, Chapter 943 FS. History–New 1-31-80, Amended 6-29-80, 7-5-81, Formerly 11-1.041, Amended 7-6-99, 8-22-00, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Fern Rosenwasser, Assistant General Counsel

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Governor and Cabinet

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 17, 2008

DEPARTMENT OF LAW ENFORCEMENT

Criminal Justice Standards and Training Commission

RULE NOS.:	RULE TITLES:
11B-27.0011	Moral Character
11B-27.00212	Maintenance of Officer Certification

PURPOSE AND EFFECT: 11B-27.0011(5): Revised to add rule language for recantation, as a defense to any violation involving perjury or false statement in a court proceeding, if the perjury or false statement occurred during the performance of work duties or in the course of an administrative investigation, and if the officer making the statement conceded such statement to be false prior to the employing agency's final disciplinary determination. The first sentence of the proposed rule language was written for court proceedings only and is a restatement of Section 837.07, F.S. The second sentence of the proposed rule language includes only "moral character violations" during the course of an internal affairs investigation and does not include misdemeanor convictions of perjury.

11B-27.00212(13): Changed the use-of-force mandatory retraining requirement from every two-years to once during an officer's 4-year mandatory retraining cycle. Revised the Mandatory Retraining Report form CJSTC-74 to reflect the new use-of-force mandatory retraining cycle. Implemented the new statutory requirement for elder abuse training, pursuant to Section 943.17296, F.S., effective July 1, 2008. This training requires the Commission's basic recruit training programs and mandatory retraining requirements to include identification of and appropriate responses for persons suffering from dementia, and identifying and investigating elder abuse.

SUMMARY: The proposed rule revisions implement the following changes: Added rule language to provide for "recantation of a false statement" that occurs during the performance of work duties or in the course of an administrative investigation. Reduced the mandatory retraining cycle for use-of-force training. Added elder abuse training for basic recruit training programs and mandatory retraining as required by the 2008 statutory revision to Section 943.17296, F.S.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 943.03(4), 943.12(1) FS.

LAW IMPLEMENTED: 943.12, 943.13, 943.135, 943.1395, 943.1701, 943.1715, 943.1716, 943.253 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: February 4, 2009, 10:00 a.m.

PLACE: 2331 Phillips Road, Tallahassee, Florida 32308

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Donna Hunt at (850)410-8615. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Donna Hunt at (850)410-8615

THE FULL TEXT OF THE PROPOSED RULES IS:

11B-27.0011 Moral Character.

(1) through (4) No change.

(a) through (b) No change.

1. through 3. No change.

(c) No change.

1. through 3. No change.

a. through b. No change.

4. No change.

a. through c. No change.

5. through 9. No change.

a. through l. No change.

10. through 12. No change.

(d) No change.

(5) A certified officer's failure to maintain good moral character as defined in subsection (4) of this rule section by committing a violation involving perjury or false statement in a court proceeding, shall not include a statement which was recanted. If the violation involving perjury or false statement is alleged to have occurred in the performance of regularly

required work duties or the course of an administrative or disciplinary investigation, a certified officer's failure to maintain good moral character as defined in subsection (4) of this rule section shall not include a statement in which the officer making the statement conceded such statement to be false prior to the employing agency's final disciplinary determination as provided for in Section 112.532(4)(b), F.S. ~~Recantation, pursuant to Section 837.07, F.S., shall be a defense to any violation involving perjury or false statement, pursuant to subsection (4) of this rule section~~.

(6) through (7) No change.

(a) through (c) No change.

(8) No change.

Specific Authority 943.03(4), 943.12(1) FS. Law Implemented 943.13(7), 943.1395(7) FS. History–New 1-7-85, Formerly 11B-27.011, Amended 7-13-87, 10-25-88, 12-13-92, 9-5-93, 1-19-94, 8-7-94, 11-5-95, 1-2-97, 7-7-99, 8-22-00, 11-5-02, 4-11-04, 11-30-04, 3-27-06, 3-21-07, 6-9-08,_____.

11B-27.00212 Maintenance of Officer Certification.

(1) through (3) No change.

(4) Continuing education or training pursuant to Section 943.135, F.S. Upon an officer's completion of the required continuing education or training the employing agency shall submit or electronically transmit to Commission staff through the Commission's ATMS, and maintain in file a completed Mandatory Retraining Report, form CJSTC-74, revised November 8, 2007, hereby incorporated by reference.

(5) No change.

(a) through (d) No change.

(6) through (12) No change.

(a) No change.

1. through 3. No change.

(b) No change.

1. through 3. No change.

(13) Use-of-Force training. An officer~~, whose mandatory retraining cycle begins on July 1, 2005 or thereafter,~~ shall, as a part of the officer's 40-hour continuing education or training every four years, be required to complete the following Use-of-Force training.

(a) No change.

1. through 5. No change.

(b) A law enforcement and correctional officer shall complete~~, once every two years,~~ Use-of-Force training pursuant to subparagraphs (13)(a)1.-5., of this rule section.

(c) A correctional probation officer shall complete~~, once every two years,~~ Use-of-Force training pursuant to subparagraphs (13)(a)2.-5., of this rule section.

~~(d) An officer, who fails to comply with the Use-of-Force training requirements within the first two years of his or her four year mandatory retraining cycle, shall satisfy these training requirements prior to the end of the four-year cycle.~~

(d)~~(c)~~ An officer's employing agency shall report the completion of Use-of-Force training to Commission staff, pursuant to (4) of this rule section. ~~prior to the close of the officer's four-year mandatory retraining cycle, by electronically transmitting a completed Mandatory Retraining Report form CJSTC-74, through the Commission's ATMS.~~

(e)~~(f)~~ An officer is permitted to substitute instruction of Use-of-Force training to satisfy the continuing education or training requirements for the officer's four-year mandatory retraining cycle.

~~(g) An officer, who fails to comply with the Use-of-Force training requirements, pursuant to paragraphs (13)(a)-(f) of this rule section, shall become an inactive Florida officer. The officer's certification shall become reactivated when the officer's employing agency electronically transmits a completed form CJSTC-74, to Commission staff, verifying the officer has met the continuing education or training requirements for the officer's four-year mandatory retraining cycle.~~

~~(h) An officer, who has a lapse in employment of less than four years, shall complete the Use-of-Force training requirements pursuant to paragraph (13)(b) or (c) of this rule section.~~

(14) No change.

(a) No change.

(b) Reporting of the compliance with this standard shall be June 30, 2008, and every two years thereafter. Documentation supporting the demonstration of proficiency skills shall be reported on the Mandatory Firearms Training Report, form CJSTC-86, revised November 8, 2007, hereby incorporated by reference, and maintained in the officer's ~~employment~~ file. The employing agency shall submit or electronically transmit to Commission staff through the Commission's ATMS, the date of completion ~~a completed form CJSTC-86~~.

(c) through (d) No change.

(15) Elder Abuse Training. As a part of basic recruit training or the officer's continuing education or training, a law enforcement officer shall be required to complete training on identifying and investigating elder abuse and neglect.

(a) Certified law enforcement officers shall complete Elder Abuse Training on or before June 30, 2011 pursuant to Section 943.17296, F.S.

(b) The training shall include instruction on the identification of and appropriate responses for persons suffering from dementia and on identifying and investigating elder abuse and neglect.

(c) Law enforcement officers who have successfully completed one of the following programs will have satisfied this training requirement:

1. CMS Application-Based Law Enforcement Basic Recruit Training Program (BRTP) number 224.

2. Florida CMS Law Enforcement BRTP number 1177.

3. Traditional Correctional Cross-Over to CMS Application-Based Law Enforcement BRTP number 1143.

4. Correctional Officer Cross-Over Training to Florida CMS Law Enforcement BRTP number 1178.

5. Traditional Correctional Probation Cross-Over to CMS Application-Based Law Enforcement BRTP number 1157.

6. Correctional Probation Officer Cross-Over Training to Florida CMS Law Enforcement BRTP number 1179.

7. CMS Law Enforcement Auxiliary Officer BRTP number 1180.

(d) Law enforcement officers who have successfully completed Crimes Against the Elderly advanced training course number 100 will have satisfied this training requirement.

(e) Law enforcement officers who have successfully completed the Elder Abuse Training for Law Enforcement course by the Department of Elder Affairs will have satisfied this training requirement.

(f) Law enforcement officers who have successfully completed the Specialized Training Program Elder Abuse Investigations course, number 1185, will have satisfied this training requirement. There are no required minimum training hours for mandatory retraining, however, training schools may teach the course as a specialized training program course requiring a minimum of four contact hours.

(g) An officer who fails to comply with the elder abuse and neglect training requirements pursuant to Section 943.17296, F.S., shall become an inactive Florida officer. The officer's certification shall become reactivated when the officer's employing agency provides Commission staff with verification that the officer has met the continuing education or training requirement.

(h) Upon an officer's completion of the required training the employing agency shall submit or electronically transmit to Commission staff through the Commission's ATMS the date of completion.

Specific Authority 943.03(4), 943.12(1) FS. Law Implemented 943.12, 943.13(11), 943.135, 943.1395(3), 943.1701, 943.1715, 943.1716, 943.253 FS. History–New 11-5-02, Amended 12-3-03, 11-30-04, 3-27-06, 3-21-07, 6-9-08, _____.

Editorial Note: See 11B-27.0023, F.A.C.

NAME OF PERSON ORIGINATING PROPOSED RULE: Donna Hunt at (850)410-8615, Bureau Chief Vickie Gardner at (850)410-8660, and Attorney Fern Rosenwasser at (850)410-7685

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Florida Department of Law Enforcement

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 17, 2008

DEPARTMENT OF LAW ENFORCEMENT

Division of Criminal Justice Information Systems

RULE NO.:	RULE TITLE:
11C-7.008	Administrative Expunction Procedures

PURPOSE AND EFFECT: Implements updated statutory requirements for the administrative expunction of Florida criminal history arrest records that are made contrary to law or by mistake.

SUMMARY: Requests for administrative expunction from the Florida criminal history file of arrests made in error or contrary to law no longer require an affidavit from the head of the arresting agency. If the person was arrested in error based on a warrant, capias, or pick-up order, the request for an administrative expunge may be made either by the head of the arresting agency or by the sheriff of the warranting county or by the state attorney of the judicial circuit where the warrant, capias or pick-up order was issued.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 943.03, 943.0581 FS.

LAW IMPLEMENTED: 943.0581 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: Wednesday, February 4, 2009, 10:00 a.m.

PLACE: Florida Department of Law Enforcement, 2331 Phillips Road, Tallahassee, Florida 32308

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Tanya Goetz, Florida Department of Law Enforcement, Criminal Justice Information Services, 2331 Phillips Road, Tallahassee, Florida 32308. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Jean Itzin, Florida Department of Law Enforcement, Criminal Justice Information Services, 2331 Phillips Road, Tallahassee, Florida 32308, (850)410-7980

THE FULL TEXT OF THE PROPOSED RULE IS:

11C-7.008 Administrative Expunction Procedures.

(1) Non-judicial records of arrest made contrary to law or by mistake will be administratively expunged by the Department, upon application by the arresting law enforcement agency, or by the person arrested or, in the case of a minor child, the parent or legal guardian of the minor person arrested. An application submitted by the person arrested~~,~~ or the parent or legal guardian of the minor person arrested, shall be supported by the endorsement of the head or chief law enforcement officer of the arresting agency or of the state attorney of the judicial circuit in which the arrest occurred.

(2) No change.

(3) An application for administrative expunction must be in writing. If submitted by the arresting law enforcement agency, the application shall be on agency letterhead, and signed by the head or chief law enforcement officer of the arresting agency~~, chief law enforcement officer~~ or his or her authorized designee. An application submitted by the person arrested or the parent or legal guardian of the minor person arrested, must be in writing and must identify the relationship of the person signing the application to the person arrested.

(4) A supporting endorsement of an application submitted by the person arrested or the parent or legal guardian of the minor person arrested, must be in writing, on agency letterhead, and signed by the head or chief law enforcement officer of the arresting agency or his or her authorized designee or by the state attorney of the judicial circuit in which the arrest occurred or his or her authorized designee.

(5) An application for administrative expunction submitted by the arresting law enforcement agency, or the supporting endorsement in the case of an application submitted by the person arrested~~,~~ or the parent or legal guardian of the minor person arrested, shall identify the arrest to be expunged by providing the following information. Written documents related to administrative expunctions shall make specific reference to identifying information, including:

(a) Name and Aliases;

(b) Sex and Race ~~Alias/Maiden Name(s)~~;

(c) Date of Birth ~~Sex~~;

(d) Social Security Number (if available, used for identification – not mandatory) ~~Race~~;

(e) Date and Time of Arrest ~~Birth~~;

(f) Original Charge(s) ~~Social Security Number (Not required)~~;

(g) FDLE Number and FBI Number (if applicable and known) ~~Date of Arrest~~;

(h) OBTS ~~Arrest~~ Number ~~and Original Charges~~;

(i) Reason for Administrative Expunction ~~FDLE Number and FBI Number (If Applicable and Known)~~;

~~(j) Reason For Administrative Expunction.~~

(6) If the person was arrested on a warrant, capias, or pick-up order, the request for an administrative expunction, or the supporting endorsement of an application submitted by the person arrested or the parent or legal guardian of the minor person arrested, may be made by the sheriff of the county where the warrant, capias, or pick-up order was issued or his or her deignee, or by the state attorney of the judicial circuit where the warrant, capias, or pick-up order was issued or his or her designee. ~~Any application for administrative expunction, whether submitted by the arresting law enforcement agency or by the person arrested or the parent or legal guardian of the minor person arrested, must be supported by an affidavit executed by the chief of the arresting law enforcement agency, sheriff, or department head of the arresting state law enforcement agency in which the affiant verifies that he or she has reviewed the record of the arrest and that the arrest was contrary to law or was a mistake. The affidavit shall include the date and time of the arrest, the name of the arresting officer, the name of the person arrested, and the crime or crimes charged and shall be submitted directly to the Department by the arresting law enforcement agency. An application which does not include this affidavit, in the form prescribed, will be rejected by the Department and a written explanation of the reason for rejection will be provided to the applicant by the Department. A copy of the rejection notice and explanation will also be provided to the arresting agency if that agency has made a submission in support of the application.~~

(7) When an administrative expunge application meets the statutory requirements, the Department will notify the arresting agency, which is then responsible for expunging its records of the arrest, and for notifying any other agency to which it provided the criminal history record information that is the subject of the administrative expunction.

(8)~~(7)~~ No application~~,~~ or endorsement~~, or affidavit~~ made under this section shall be admissible as evidence in any judicial or administrative proceeding or otherwise be construed in any way as an admission of liability in connection with an arrest.

(9)~~(8)~~ The procedures by which an individual may secure an administrative correction of the criminal history record pertaining to the individual are set out in Chapter 11C-8, F.A.C. Non-criminal arrest records which are mistakenly or improperly forwarded to the Department for processing and retention as criminal history records will be removed as an administrative correction ~~expunge~~ by the Department.

Specific Authority 943.03, 943.0581 FS. Law Implemented 943.0581 FS. History–New 8-5-92, Amended 3-21-07, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Jean Itzin

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Governor and Cabinet

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 17, 2008

DEPARTMENT OF LAW ENFORCEMENT

Division of Criminal Justice Information Systems

RULE NOS.:	RULE TITLES:
11C-10.001	Definitions
11C-10.002	Procedures

PURPOSE AND EFFECT: To implement procedures regarding the collection and submission of DNA specimens for persons missing over 90 days, based upon recent statutory changes.

SUMMARY: The amended rule language implements the procedures for the collection and submission of DNA for persons missing over 90 days.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 937.021(7), 937.022, 943.03(4) FS.

LAW IMPLEMENTED: 937.021(6), 937.022 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: Wednesday, February 4, 2009, 10:00 a.m.

PLACE: Florida Department of Law Enforcement, 2331 Phillips Road, Tallahassee, Florida 32308

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Dinah Johnson at (850)410-8583. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Dinah Johnson, Florida Department of Law Enforcement, Missing Endangered Persons Information Clearinghouse, 2331 Phillips Road, Tallahassee, Florida 32308

THE FULL TEXT OF THE PROPOSED RULES IS:

11C-10.001 Definitions.

(1) “Approved biological specimen” shall mean either a direct reference sample or a family reference sample.

(2) “Buccal swab” shall mean epithelial cells collected from the cheek in the oral cavity using a sterile cotton-tipped swab.

(3) “Direct reference sample” shall mean any known DNA standard or biological specimen, which is known to originate from the missing child or adult. Examples include a known medical blood sample, razor, or toothbrush.

(4) “Family reference sample” shall mean a DNA specimen that is obtained from a biologically related family member of a missing child or adult.

(5) “Family reference sample collection kit” shall mean an approved DNA collection kit that provides a means of collecting DNA reference samples from biologically related family members of a missing child or adult. These DNA collection kits are assembled by the University of North Texas Center for Human Identification, which includes a buccal swab collection kit or the FBI National Missing Person DNA Database, which utilizes a FBI blood cell collection kit. Each kit contains DNA collection instructions, consent forms for the donor, missing person information forms, and any items provided to collect DNA samples.

(6) The terms missing child or adult shall have the same meanings as provided for in Section 937.0201, F.S.

Specific Authority 943.03(4), 937.021(7) FS. Law Implemented 937.021, 937.022 FS. History–New _____.

11C-10.002 Procedures.

(1) If a missing child or adult is not located within 90 days after the missing child or missing adult report is filed, the law enforcement agency that accepted the report shall attempt to obtain a biological specimen for DNA analysis from the missing child or missing adult or from biologically related family members. The law enforcement agency can provide a biological specimen for DNA analysis prior to the expiration of the 90-day period.

(2) Submission of a direct reference sample of the missing child or adult.

(a) The law enforcement agency shall submit a direct reference sample, which can include a known medical blood sample, toothbrush, or razor, to the University of North Texas (UNT) Center for Human Identification Center at 3500 Camp Bowie Blvd., Fort Worth, Texas 76054, phone number 1(800)763-3147, or the Federal Bureau of Investigation (FBI) National Missing Person DNA Database, FBI Laboratory, Evidence Control Unit, Samples for National Missing Person DNA Database, 2501 Investigation Parkway, Quantico, VA 22135, phone (703)632-7582. Direct reference sample submission instructions are also available on the CJNet on the Missing Endangered Persons Information Clearinghouse Website, under the DNA link, URL address: http://mcic.flcjn.net/MCICsearch, or contact the Florida

Department of Law Enforcement Missing Endangered Persons Information Clearinghouse, P. O. Box 1489, Tallahassee, Florida 32302-1489, phone number 1(888)356-4774.

(b) A direct reference sample shall be accompanied by family reference DNA samples. If no family reference DNA samples exist, the law enforcement agency shall include a written notice at the time of the direct reference sample submission.

(c) The law enforcement agency shall follow the instructions provided by the UNT or the FBI for the collection, labeling, storage, handling and submission of a direct reference sample.

(d) If no direct reference sample exists, the law enforcement agency shall attempt to obtain family reference DNA samples for submission.

(3) Submission of family reference samples. The law enforcement agency has the option of collecting buccal swabs or blood samples:

(a) Family reference sample kits for buccal swab collection are available at no cost from the UNT.

(b) Family reference sample kits for blood sample collection are available at no cost from the FBI. The withdrawal of blood for purposes of this section shall be performed in a medically approved manner using the FBI's family reference sample collection kits, and only by or under the supervision of a physician, registered nurse, licensed practical nurse, and any duly licensed medical personnel.

(c) The law enforcement agency shall attempt to obtain one family reference DNA sample from at least two different biologically related family members of the missing child or adult.

(d) The priority of sample submission is as follows: biological mother, biological father, biological siblings, biological children, maternal relatives, and paternal relatives.

(e) The biologically related family member of the missing child or adult must be positively identified by the law enforcement agency prior to submission of the DNA sample. An example of proof of identification would be a state or federal government issued identification card containing a photograph of the donor.

(f) The law enforcement agency shall follow the instructions provided by the UNT or the FBI for the collection, labeling, storage, handling and submission of family reference samples.

(4) Law enforcement state (FCIC) and national (NCIC) database entry requirements:

(a) Upon receipt of the a lab case identification number from UNT or FBI, the law enforcement agency shall modify the DNA fields in the missing person entry of the Florida Crime Information Center (FCIC) and National Crime Information Center (NCIC) databases to indicate that DNA specimens were collected and submitted. The DNA location field (DLO) of the missing person entry shall include information regarding the name of the laboratory, the lab case identification number, contact person, and the type of specimen submitted.

(b) If a match occurs between the DNA profiles for a missing child or adult and an unidentified person, then the law enforcement agency will be notified by the FBI or the UNT.

(c) Once the missing child or adult is located or identified, the law enforcement agency shall provide the UNT or the FBI with written notification on law enforcement agency letterhead.

Specific Authority 943.03(4), 937.021(7) FS. Law Implemented 937.021, 937.022 FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Dinah Johnson

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Governor and Cabinet

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 17, 2008

DEPARTMENT OF LAW ENFORCEMENT

Office of Inspector General

RULE NOS.:	RULE TITLES:
11N-1.002	Criteria
11N-1.0022	Drug Control Investigative Funding
11N-1.0023	Criminal Gang Investigative Funding
11N-1.003	Limitations on Violent Crime Investigative Reimbursement Funding
11N-1.0031	Limitations on Matching Drug Control Investigative Funding
11N-1.0032	Limitations on Criminal Gang Investigative Funding
11N-1.0051	Procedures for Funding Requests for Drug Control Investigative Funding
11N-1.0052	Procedures for Funding Requests for Criminal Gang Investigative Funding
11N-1.006	Contributions

PURPOSE AND EFFECT: Implements updated statutory criteria for funding and clarifies existing funding language.

SUMMARY: Expands the duties of the Violent Crime and Drug Control Council to provide proactive criminal gang investigative funding and to clarify funding criteria for agencies receiving funding from the Violent Crime and Drug Control Strategy Implementation Account.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 943.03(4), 943.042 FS.

LAW IMPLEMENTED: 943.031, 943.042 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):

DATE AND TIME: Wednesday, February 4, 2009, 10:00 a.m.

PLACE: Florida Department of Law Enforcement, 2331 Phillips Road, Tallahassee, Florida 32308

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: Joyce Gainous-Harris at (850)410-7096. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Joyce Gainous-Harris, Florida Department of Law Enforcement, Investigations and Forensic Science Program, 2331 Phillips Road, Tallahassee, FL 32308

THE FULL TEXT OF THE PROPOSED RULES IS:

11N-1.002 Criteria.

The Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account shall be used:

(1) To provide emergency supplemental funds to:

(a) through (c) No change.

(2) To provide matching funding, as provided for in Rules 11N-1.0022 and 11N-1.0023, F.A.C., to multi-agency or statewide drug control, criminal gang, or illicit money laundering investigative or task force efforts that:

(a) Significantly contribute to achieving the state's goal of reducing drug-related crime as articulated by the Office of Drug Control;

(b) Represent significant criminal gang investigative efforts;

(c)~~(b)~~ Represent a significant illicit money laundering investigative effort; or

(d)~~(c)~~ Otherwise significantly support statewide strategies developed by the Statewide Drug Policy Advisory Council established under Section 397.333, F.S.

(3) No change.

(4) Funding approval or authorization shall be as follows:

(a) The Violent Crime and Drug Control Council, as described in Section 943.031, F.S., shall approve funding for Violent Crime Investigative Reimbursement and Emergency Violent Crime Funding.

(b) The Drug Control Strategy and Criminal Gang (DCSCG) Committee, as described in Section 943.031, F.S., shall authorize funding for Drug Control and Criminal Gang Investigative Funding.

(c) The Victim Witness Protection Review Committee, as described in Section 943.031, F.S., shall approve funding for the Victim Witness Protection Program.

(5) The Chair of the Council shall be selected from Council members eligible for membership on the Victim and Witness Protection Review Committee as defined at Section 943.031(8) F.S., and who shall also serve as Chair of the Victim and Witness Protection Review Committee and the Drug Control Strategy and Criminal Gang Committee as defined at Section 943.031(6), F.S.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 3-10-94, Amended 10-10-95, 10-25-01, 11-5-02, 3-21-07, 6-9-08, _____.

11N-1.0022 Drug Control Investigative Funding.

(1) In determining whether requests for drug control funding relate to multi-agency or statewide drug control or illicit money laundering investigative or task force efforts that:

(a) through (b) No change.

(c) Otherwise significantly support statewide strategies developed by the Statewide Drug Policy Advisory Council, the following criteria shall be considered by the DCSCG Committee:

1. through 2. No change.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 10-25-01, Amended 11-5-02, 12-3-03, 3-27-06, _____.

1N-1.0023 Criminal Gang Investigative Funding.

(1) In determining whether requests for criminal gang investigative funding relate to criminal proactive investigative efforts that:

(a) Significantly contribute to achieving the state's goal of reducing criminal gang activity.

(b) Represent a significant criminal gang investigative effort; or

(c) Otherwise significantly support statewide strategies developed by the Statewide Drug Policy Advisory Council, the following criteria shall be considered by the DCSCG Committee:

1. Mandatory Factors:

a. The investigative effort focuses on a criminal gang shown to have, or reasonably believed of having, activities such that involvement of multiple investigative agencies is necessary; and

b. At least two agencies of the State of Florida, counties, cities, or combination thereof within the State of Florida are involved; and

c. The investigative effort demonstrates a commitment of participating agencies to cooperate with one another in a collaborative investigative effort; and

d. The criminal gang to be investigated has, or is reasonably believed to have, a structure that directs, finances, and engages in criminal gang activity and related crimes (such as drug trafficking, money-laundering, organized crime, and crimes of violence) that have the same or similar intents, results, accomplices, victims, or methods of commission or that otherwise are interrelated by distinguishing characteristics and are not isolated incidents; and

e. The proposed investigative effort demonstrates a specific strategy:

(I) To achieve successful prosecutions of those within the criminal gang who hold a position of organizer, supervisor, or any other position of authority or who obtains substantial assets or resources from the illegal acts of the criminal gang being investigated as they may become identified; and

(II) To utilize a multi-agency and cross-discipline approach to disrupt and dismantle the criminal gang operation via seizures of assets, and organized crime investigations and prosecutions, or similar efforts.

f. The proposed investigative plan demonstrates a level of participating agency resource commitment that suggests a substantial likelihood of investigative and prosecution success; and

g. The proposed effort includes a commitment from one or more State Attorneys in Florida, U.S. Attorneys in Florida, or Florida's Statewide Prosecutor having jurisdiction over the activities of the criminal gang under investigation to assist and support the investigation, through efforts such as issuance of subpoenas, use of grand juries, obtaining search warrants, securing court orders regarding the interception of communications, coordinating multiple prosecutions, assisting in securing plea agreements with those in the criminal gang organization in return for cooperation and testimony, and certifying witnesses for witness protection under applicable law and a commitment to cooperate with other prosecuting entities having jurisdiction over activities of the criminal gang to maximize the success of the investigative effort.

h. The proposed investigative effort shall ensure that all known targets of a criminal gang investigation proposed to be funded by the Council funds shall be entered into the "InSite" database maintained by the Florida Department of Law Enforcement. The funding request shall indicate that such entry has been accomplished. All future identified targets shall be entered into "Insite." All criminal gang seizures related to criminal gang Council funded investigations shall be entered into "InSite." Upon failure to make such entry, the Council is authorized to suspend funding not yet provided and to direct refund of all unexpended funds previously provided by the Council.

2. Non-Mandatory Factors Enhancing the Significance of the Proposed Effort:

a. The activities of the criminal gang under investigation are responsible for known specified significant criminal activity in multiple regions of the State;

b. The proposed investigative plan has identified the types and methods of significant criminal violations under state or federal law actually, or suspected to be, occurring, and articulates a dedicated strategy to identify, trace, and address persons, institutions or other entities that are likely involved;

c. The criminal gang under investigation is known to have and identifies, or is reasonably believed to have, assets and property that constitute contraband under Florida or other law that may be seized and forfeited and the investigative plan contains a strategy to identify such assets and property and to use forfeiture options to disrupt the underlying criminal gang;

d. Persons in the criminal gang under investigation are, upon successful prosecution, likely to receive sentences involving substantial terms of incarceration in state or federal prisons, paying a substantial fine, or both;

e. The proposed investigative effort appears to be likely to be lengthy and complex (as specified in Rule 11N-1.0021, F.A.C.), and will likely require sophisticated electronic, undercover or other investigative techniques;

f. The criminal gang under investigation is such that if investigation and prosecutions are successful it is likely that significant reductions in criminal gang activity within the State of Florida will result; or

g. The proposal presents an innovative plan with a likelihood of success for addressing a significant criminal gang organization. In determining what constitutes a significant criminal gang, the Council shall consider the following factors related to the criminal gang under investigation as may be demonstrated in the request:

i. The number of persons believed to be involved in the criminal gang's illicit activities;

ii. The regional, statewide, national, or multi-national impact upon ongoing criminal activity expected to occur if the investigation successfully disrupts the criminal gang under investigation;

iii. The perceived potential or propensity of the criminal gang for violence, injury to innocent persons, or for any activity reasonably believed to be hazardous to persons or property;

iv. Known or suspected links of the criminal gang or its members to individuals or organizations suspected to be or known to be involved in acts of terrorism as defined at Section 775.30, F.S., or in promoting, planning, or executing acts of violence to further political or other beliefs; and

v. The anticipated reduction in the numbers of criminal gangs or criminal gang members will be curtailed or restricted if the investigation successfully disrupts the criminal gang under investigation.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New _____.

11N-1.003 Limitations on Violent Crime Investigative Reimbursement Funding.

(1) Requests for Violent Crime Investigative Reimbursement Funding.

(a) through (b) No change.

(c) Funding provided under this section from the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account is available to a Florida state or local law enforcement agency and such funding shall be used ~~agencies~~ for ~~violent crime~~ investigative purposes directly linked to the investigative effort. As used herein, "l~~L~~aw enforcement agency ~~agencies~~" is defined as a Florida ~~include~~ police department, a Florida sheriff's~~'s~~ office~~s~~, a regional office of the Florida Department of Law Enforcement or other Florida ~~and~~ state law enforcement agency ~~agencies~~, or a troop of the Florida Highway Patrol.~~,~~ H~~h~~owever, ~~for the purposes of this rule,~~ the term excludes the Department of Financial Services, state attorneys' ~~prosecutors'~~ offices, and the Office of Statewide Prosecution except for resources provided by such offices exclusively dedicated to investigative efforts approved for funding by the Council ~~criminal investigations~~.

(d) through (f) No change.

(2) through (3) No change.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 3-10-94, Amended 10-10-95, 10-25-01, 12-3-03, _____.

11N-1.0031 Limitations on Drug Control Investigative Funding.

(1) Requests for funding from the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account shall be limited to case-related investigative expenses, salary and overtime for the efforts of officers and employees directly linked to a funded investigation and other expenses related to investigations authorized ~~approved~~ for funding by the DCSCG Committee ~~Council~~.

(2) Each funding request shall designate a lead investigative agency that will serve as the liaison between the DCSCG Committee ~~Council~~ and the participating agencies for the purposes of coordinating the collection of information and in disbursing funds authorized ~~approved~~ by the DCSCG Committee ~~Council~~. Each participating agency shall agree to promptly provide requested information to the DCSCG Committee ~~Council~~, to provide regular performance reports and information related to funded investigations as required by the DCSCG Committee ~~Council~~, retain documentation and proof of expenditures or personnel efforts as may be required by the DCSCG Committee ~~Council~~, and submit to any audit or review of the use of received funds as may be required by the DCSCG Committee ~~Council~~.

(3) If a new ~~an additional~~ agency is brought into the investigation after funding has already been appropriated and no additional monies are being sought and there is no change of focus of the investigation, a lead investigative agency is authorized to request that the new ~~additional~~ agency be permitted to share in C~~c~~ouncil funds for the investigation.

(a) No change.

(b) Pursuant to Rule 11N-1.0031, F.A.C., the new agency shall guarantee its agreements are completed and obtain agency match funding before presenting its package, with the lead agency's endorsement, to the ~~Chairperson of the~~ Council Chairperson.

(c) The Council Chairperson shall have the ability to make interim ratification of new agencies' ~~additional agencies~~ participation in a specific funded investigation until the next regularly scheduled council meeting at which time the DCSCG Committee ~~entire Council~~ shall vote upon the issue.

(4) Supplemental funding requests shall be presented by the lead investigative agency at the next regularly scheduled Council meeting. Mutually agreed upon investigations may be adopted by reference by the DCSCG Committee ~~Council~~ when there is no change in the original investigative focus and mission of the originally funded investigation.

(5) Funding from the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account is available ~~only~~ to a Florida state or local law enforcement agency and such funding shall be used for investigative purposes directly linked to the investigative effort authorized ~~approved~~ for funding by the DCSCG Committee ~~Council~~. As used herein, "law enforcement agency" is defined as ~~include~~ a Florida police department, a Florida sheriff's office, a regional office of the Florida Department of Law Enforcement or other Florida state law enforcement agency, ~~the Department of Financial Services,~~ or a troop of the Florida Highway Patrol. However, the term excludes the Department of Financial Services, state attorneys' offices, and the Office of Statewide Prosecution except for resources provided by such offices exclusively dedicated to investigative efforts approved for funding by the Council.

(6) Limits Upon Drug Control Funding.

(a) through (b) No change.

(c) In each agency fiscal year, payment of overtime with Council funds shall not exceed $10,000 per officer or employee dedicated to the funded investigative effort~~s~~ within the officer or employee agency's fiscal year. The $10,000 limit applies to the officer or employee's combined hours dedicated to all Council funded investigative efforts within the fiscal year.

(d) through (e) No change.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 10-25-01, Amended 12-3-03, 3-27-06, 3-21-07, _____.

11N-1.0032 Limitations on Criminal Gang Investigative Funding.

(1) Requests for proactive investigative funding from the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account shall be limited to case-related investigative expenses, salary and overtime for the efforts of officers and employees directly linked to a funded investigation and other expenses related to investigations authorized for funding by the DCSCG Committee.

(2) Each funding request shall designate a lead investigative agency that will serve as the liaison between the DCSCG Committee and the participating agencies for the purposes of coordinating the collection of information and in disbursing funds authorized by the DCSCG Committee. Each participating agency shall agree to promptly provide requested information to the DCSCG Committee, to provide regular performance reports and information related to funded investigations as required by the DCSCG Committee, retain documentation and proof of expenditures or personnel efforts as may be required by the DCSCG Committee, and submit to any audit or review of the use of received funds as may be required by the DCSCG Committee.

(3) If an additional agency is brought into the investigation after funding has already been appropriated and no additional monies are being sought and there is no change of focus of the investigation, a lead investigative agency is authorized to request that the additional agency be permitted to share in council funds for the investigation.

(a) The lead agency shall verify and endorse the new agency's participation and that all requirements of Rule 11N-1.0032, F.A.C., will be fulfilled by the new agency.

(b) The new agency shall guarantee its agreements are completed before presenting its package, with the lead agency's endorsement, to the Council Chairperson.

(c) The Council Chairperson shall have the ability to make interim ratification of additional agencies' participation in a specific funded investigation until the next regularly scheduled council meeting at which time the DCSCG Committee shall vote upon the issue.

(4) Supplemental funding requests shall be presented by the lead investigative agency at the next regularly scheduled Council meeting. Mutually agreed upon investigations may be adopted by reference by the DCSCG Committee when there is no change in the original investigative focus and mission of the originally funded investigation.

(5) Disbursement of proactive investigative funding from the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account is available to a Florida state or local law enforcement agency and such funding shall be used for investigative purposes directly linked to the investigative effort authorized for funding by the DCSCG Committee. As used herein, "law enforcement agency" is defined as a Florida police department, a Florida sheriff's office, a regional office of the Florida Department of Law Enforcement or other Florida state law enforcement agency, or a troop of the Florida Highway Patrol. However, the term excludes the Department of Financial Services, state attorneys' offices, and the Office of Statewide Prosecution except for resources provided by such offices exclusively dedicated to investigative efforts approved for funding by the Council.

(6) Limits Upon Criminal Gang Funding.

(a) The maximum funding provided by the Council on a single investigation shall be $100,000. However, an approved investigative effort may consist of multiple investigations, each of which may receive funding up to $100,000.

(b) No law enforcement agency as defined herein may receive more than $200,000 in Council gang investigative or drug control funds during the agency's fiscal year.

(c) In each agency fiscal year, payment of overtime with Council funds shall not exceed $10,000 per officer or employee dedicated to funded investigative efforts within the officer or employee agency's fiscal year. The $10,000 limit applies to the officer or employee's combined hours dedicated to all Council funded investigative efforts within the fiscal year.

(d) The Council may fund all, a portion, or none of a proposed investigative effort seeking proactive criminal gang funding.

(e) Previously-approved criminal gang investigation initiatives are eligible for additional funding from the Council, up to the funding limits set by Rules 11N-1.0031 and 11N-1.0032, F.A.C., and Section 943.031, F.S. In order to receive consideration for additional funding, an entity seeking such consideration must demonstrate:

1. That it has complied fully with reporting and accountability obligations for the initial funding, and;

2. That the request for additional funding conforms with Council requirements for funding, and comports with the originally-funded request, and;

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New _____.

11N-1.0051 Procedures for Funding Requests for Drug Control Investigative Funding.

(1) No change.

(2) All requests for drug control investigative effort funds from the DCSCG Committee ~~Violent Crime and Drug Control Council (Council)~~ must be developed in conjunction with, and approved by, the RCT in the region from in which the lead requesting agency is located. No request submitted without the endorsement of the RCT will be considered by the DCSCG Committee ~~Council~~.

(3) through (4) No change.

(5) A completed application for funding shall be submitted by the Chair of the RCT so that it is received at least 30 days prior to the next scheduled Violent Crime and Drug Control

Council meeting. Requests shall be mailed to: Florida Violent Crime and Drug Control Council, c/o Florida Department of Law Enforcement, P. O. Box 1489, Tallahassee, Florida 32302-1489, Attn.: Investigations and Forensic Science Program. ~~Submissions from a Regional Drug Enforcement Coordinating Team shall be made to the Department of Law Enforcement's Investigations and Forensic Science Program (IFS). Materials being submitted shall be secured and transmitted in a manner to assure that the criminal investigative and criminal intelligence information contained is not compromised.~~

(6) No change.

(7) The IFS shall present to the DCSCG Committee ~~Council~~ all cases forwarded to it by the RCTs, indicating its prioritization determinations at a meeting of the Council. The presentation must include a recommendation of which cases IFS believes should receive funding priority and the amount of drug control funding recommended and may identify the relative strengths and weaknesses of the cases under consideration in meeting the underlying goals of Council funding.

(8) The DCSCG Committee ~~Council~~ will make its drug control funding decisions based upon the information presented to it by IFS, or otherwise made available at a Council meeting, and the availability of funds for use by the DCSCG Committee ~~Council~~. The DCSCG Committee ~~Council~~ may direct that approved funding shall be paid in a lump sum or in installments. The DCSCG Committee ~~Council~~ may fund all, a portion, or none of a request presented to it.

(9) Denial of all or a part of a request shall not disqualify the request from future consideration by the DCSCG Committee ~~Council~~. However, any such request will be considered a new funding request and must be evaluated and approved through the process set forth in this rule, beginning with consideration and approval by the RCT.

(10) No change.

(11) If after receipt of funds, it appears that a funded investigative effort will substantially depart from the focus and effort originally authorized ~~approved~~ by the DCSCG Committee ~~Council~~, the agencies receiving Council funds shall suspend use of such funds and shall contact the Chair of the RCT and describe the change of focus and effort.

(a) If the new focus and effort is of a type that could be considered for Council funding, the RCT and the participating agencies shall secure DCSCG Committee authorization ~~Council approval~~ for the continued use of Council funds by the funded agencies. Any such request shall be evaluated and approved through the process set forth in this rule, beginning with the consideration and approval by the RCT, but shall be expedited to minimize and negative effect the suspension of spending of Council funds may have on the ongoing investigation.

(b) If authorization for continued use of Council funds must be considered prior to the next regular meeting of the Council, the DCSCG Committee ~~Council~~ may consider such requests at a special meeting by phone or videoconference.

(c) The DCSCG Committee ~~Council~~ may endorse changes of focus or efforts and authorize the continued use of Council funds when receiving progress reports during regularly scheduled meetings provided that the RCT and the IFS endorse the new focus or efforts for such continued funding.

(12) No change.

(13) Agencies seeking drug control funding under this section shall cooperate with the RCT in the agencies' area, and provide all information as requested by the RCT to assist in the preparation of a funding request, including information to identify the amounts of agency funds being committed by each participating agency to be matched by Council drug control funds. The head of each requesting agency that seeks to receive Council drug control funds shall include in the submission to the RCT a certification in writing that to the agency head's best knowledge and belief, the request complies with the requirements established by law and this rule for funding. The agency head shall also agree to provide requested information to the DCSCG Committee ~~Council~~ to assist the DCSCG Committee ~~Council~~ in its performance-monitoring obligations and shall agree to retain proof and documentation as may be required by the DCSCG Committee ~~Council~~ and to submit to any audits or reviews of agency utilization of Council funds or funds derived from any Council-funded investigative effort as may be performed. The request shall be accompanied by Form FDLE/IFS-003 Drug Control, Criminal Gang, & Money Laundering Application, revised 10/01/08, and Form FDLE/IFS-006, the State Financial Assistance Form, ~~both~~ revised 08/01/07, incorporated by reference.

(14) Funding Calculations.

(a) In calculating the amount being provided as an agency match, the DCSCG Committee ~~Council~~ shall consider:

1. through 2. No change.

(b) In calculating the amount being provided by a requesting agency for which matching Council funds may be provided, the DCSCG Committee ~~Council~~ shall not consider:

1. through 2. No change.

(15) Council-provided funds shall not be used for any purposes by the requesting agency in calculating its agency match. Where an employee's overtime has been pledged by an agency as a match, no Council-provided funds may be used for the employee's overtime until such time as the agency's match overtime funding has been completely expended. Council funds shall not be used to purchase or lease vehicles, vessels, aircraft or conveyances, computer equipment, or buildings or the maintenance or repair of any such property or equipment. Council funds shall not be used to pay employee base salaries. In each agency's fiscal year, up to $10,000 in Council funds may be applied to an employee's overtime (including benefits

and taxes) for efforts dedicated exclusively to the funded investigative effort. Council funds may be used for the temporary rental of property or equipment for an undercover operation in support of the investigative effort, or for use in surveillance activities tied to the investigative effort. Council funds may be utilized to pay overtime of agency employees' efforts directly in support of the funded investigative effort, limited to $10,000 per employee in the employee's agency's fiscal year. The $10,000 limit applies to the employee's combined hours dedicated to all Council funded investigative efforts within the fiscal year.

(16) Council Funding Documentation.

(a) Agencies receiving drug control funding under this section shall provide a written bi-annual report of expenditures of Council funds and of the progress of the investigative effort. The report shall be prepared in consultation with the RCT and submitted by the RCT through the IFS for compilation and presentation at a scheduled Council meeting. Form FDLE/IFS-004, the Violent Crime and Drug Control Council Bi-Annual Report, revised 10/01/08 ~~08/01/07~~, incorporated by reference, shall be utilized to make the report. In addition, the DCSCG Committee ~~Council~~ may require oral progress reports to be made at Council meetings by a representative of the RCT or a designee of the lead investigative agency in a funded investigative effort.

(b) Agencies receiving Council funding shall retain documentation supporting the amounts and purposes of expenditures made from Council funds, the amounts and purposes of expenditure of agency match funds, the performance and accomplishments of the investigative efforts, and shall make these available to the DCSCG Committee ~~Council~~ upon request. With regard to agency personnel assigned to investigative efforts receiving Council funds, each agency shall retain, and make available to the DCSCG Committee ~~Council~~ as requested, each employee's official time and leave records and such other documentation demonstrating the time devoted by the employee to the funded investigative effort, but these records shall not be submitted with Form FDLE/IFS-004.

(c) Agencies receiving Council funding shall provide such other information as required by the DCSCG Committee ~~Council~~ or the IFS in its capacity as support staff, to assist in preparing its annual report to the Legislature, to assist audits of DCSCG Committee ~~Council~~ activities, or to assist the DCSCG Committee ~~Council~~ and IFS in fulfilling their role to monitor the performance of funded investigations.

(17) through (18) No change.

(19) If agencies receiving Council funding fail to submit the required Form FDLE/IFS-004, by the stated deadline, the Council Chairperson in consultation with FDLE/IFS is authorized to demand ~~request~~ that all unexpended funds be returned within 30 days. Upon such a finding, the Agency Head of each funded agency will be notified in writing as to the manner in which such funds must be returned. Any agency that is delinquent in submitting Form FDLE/IFS-004 by 90 or more days shall be subject to this provision.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 10-25-01, Amended 12-3-03, 3-27-06, 3-21-07, 6-9-08, _____.

11N-1.0052 Procedures for Funding Requests for Criminal Gang Investigative Funding.

(1) The Department of Law Enforcement has established a regional coordinating team (RCT) in each regional office. These RCTs coordinate the identification and development of criminal gang investigative efforts that significantly contribute to achieving the state's goal of reducing criminal gang activity. The identified goals should represent "significant criminal gang investigative efforts", as used herein, eligible for proactive funding, or that otherwise significantly support statewide strategies. Each RCT will be under the direction of the Florida Department of Law Enforcement Special Agent in Charge for the area of the state in which the RCT operates. The RCT should be made up of representatives of state, local, and federal law enforcement and prosecuting entities working within the area.

(2) All funding requests for criminal gang investigative efforts from the DCSCG Committee must be developed in conjunction with, and approved by, the RCT in the region from which the lead requesting agency is located. No request submitted without the endorsement of the RCT will be considered by the DCSCG Committee.

(3) Prior to submitting funding requests for criminal gang investigative efforts to the Department of Law Enforcement for review and consideration for Council funding, the RCT shall assure that the various requirements of this rule have been satisfied. The RCT shall discuss each mandatory criteria element stated in this rule, explaining in detail how the criteria is met. In addition, the RCT shall identify and discuss each non-mandatory criteria identified in this rule reasonably applicable to the request. The RCT shall assure that the funding proposal has been explained in sufficient detail to promote a fair review and evaluation of the request by the Department and the DCSCG Committee.

(4) All submissions to the Department from a RCT must be approved by the RCT and deemed complete, as indicated by the written certification of the chair of the RCT.

(5) A completed application for funding shall be submitted by the Chair of the RCT so that it is received at least 30 days prior to the next scheduled Violent Crime and Drug Control Council meeting. Requests shall be mailed to: Florida Violent Crime and Drug Control Council, c/o Florida Department of Law Enforcement, P. O. Box 1489, Tallahassee, Florida 32302-1489, Attn.: Investigations and Forensic Science Program.

(6) The IFS will receive and review all submissions from the various RCTs utilizing the criteria of this rule, and shall prioritize from the pending submissions those proposals that best meet the criteria of this rule and are determined to be criminal gang investigative efforts that are most likely to significantly contribute to achieving the state's goal of reducing criminal gang activity.

(7) The IFS shall present to the Drug Control Strategy and Criminal Gang (DCSCG) Committee all cases forwarded to it by the RCTs, indicating its prioritization determinations at a meeting of the Council. The presentation must include a recommendation of which cases IFS believes should receive funding priority and the amount of proactive criminal gang funding recommended and may identify the relative strengths and weaknesses of the cases under consideration in meeting the underlying goals of Council funding.

(8) The DCSCG Committee will make its criminal proactive decisions based upon the information presented to it by IFS, or otherwise made available at a Council meeting, and the availability of funds for use by the Council. The DCSCG Committee may direct that approved funding shall be paid in a lump sum or in installments. The DCSCG Committee may fund all, a portion, or none of a request.

(9) Denial of all or a part of a request shall not disqualify the request from future consideration by the DCSCG Committee. However, any such request will be considered a new funding request and must be evaluated and approved through the process set forth in this rule, beginning with consideration and approval by the RCT.

(10) Council-provided criminal gang funds shall be expended in a manner consistent with the investigative purposes approved by the Council.

(11) If after receipt of funds, it appears that a funded investigative effort will substantially depart from the focus and effort originally authorized by the DCSCG Committee, the agencies receiving Council funds shall suspend use of such funds and shall contact the chair of the RCT and describe the change of focus and effort.

(a) If the new focus and effort is of a type that could be considered for Council funding, the RCT and the participating agencies shall secure DCSCG Committee authorization for the continued use of Council funds by the funded agencies. Any such request shall be evaluated and authorized through the process set forth in this rule, beginning with consideration and approval by the RCT, but shall be expedited to minimize any negative effect the suspension of spending of Council funds may have on the ongoing investigation.

(b) If authorization for continued use of Council funds must be considered prior to the next regular meeting of the Council, the DCSCG Committee may consider such requests at a special meeting by phone or videoconference.

(c) The DCSCG Committee may endorse changes of focus or efforts and authorize the continued use of Council funds when receiving progress reports during regularly scheduled meetings provided that the RCT and the IFS endorse the new focus or efforts for such continued funding.

(12) In order to assure careful consideration of original requests for criminal proactive and resubmitted requests for funding that have been previously denied, all written requests, to include completed application forms, case synopses, financial forms, and approvals shall be submitted by the chair of the RCT to the IFS no later than 30 days prior to the meeting of the Council in which the request for funding might be considered.

(13) Each agency seeking criminal proactive under this section shall cooperate with the RCT in the agencies' area, and provide all information as requested by the RCT to assist in the preparation of a funding request, including information to identify the amounts of agency funds being requested by the participating agency. The head of each requesting agency that seeks to receive Council criminal gang funds shall include in the submission to the RCT a certification in writing that to the agency head's best knowledge and belief, the request complies with the requirements established by law and this rule for funding. The agency head shall also agree to provide requested information to the Council to assist the Council in its performance-monitoring obligations and shall agree to retain proof and documentation as may be required by the Council and to submit to any audits or reviews of agency utilization of Council funds or funds derived from any Council-funded investigative effort as may be performed. The request shall be accompanied by Form FDLE/IFS-003, Drug Control, Criminal Gang & Money Laundering Application, revised 10/01/08, and Form FDLE/IFS-006, the State Financial Assistance Form, revised 08/01/07, incorporated by reference.

(14) Funding Calculations.

(a) In calculating the amount being provided as an agency match, the DCSCG Committee shall consider:

1. The base salary (including benefits and taxes) and overtime compensation pledged (including benefits and taxes) of agency employees for that portion of the employees' efforts dedicated exclusively to the proposed investigative effort, and

2. Normal operating costs directly attributable to the proposed investigative effort as specifically identified by the requesting agency, subject to the exclusions listed below.

(b) In calculating the amount being provided by a requesting agency for which matching Council funds may be provided, the DCSCG Committee shall not consider:

1. Funding received by the agencies from federal sources or

2. Funding utilized for:

a. Purchases of equipment that will be retained in a participating agency's inventory;

b. The cost of purchased vehicles, vessels, aircrafts, or conveyances;

c. Any expense or purchase that appears to be incidental to, or otherwise failing to be shown to substantially support, the proposed investigative effort;

d. Seminar and training expenses for employees or officers assigned to the proposed effort; and

e. Rental or purchases of buildings and costs associated with the use or operation of such buildings, such as utilities and maintenance.

(15) Council-provided funds shall not be used to purchase or lease vehicles, vessels, aircraft or conveyances, computer equipment, or buildings or the maintenance or repair of any such property or equipment. Council funds shall not be used to pay employee base salaries. In each agency's fiscal year, up to $10,000 in Council funds may be applied to an employee's overtime (including benefits and taxes) for efforts dedicated exclusively to the funded investigative effort. Council funds may be used for the temporary rental of property or equipment for an undercover operation in support of the investigative effort, or for use in surveillance activities tied to the investigative effort. Council funds may be utilized to pay overtime of agency employees' efforts directly in support of the funded investigative effort, limited to $10,000 per employee in the employee's agency's fiscal year. The $10,000 limit applies to the employee's combined hours dedicated to all Council funded investigative efforts within the fiscal year.

(16) Council Funding Documentation.

(a) Agencies receiving proactive criminal gang funding under this section shall provide a written bi-annual report of expenditures of Council funds and of the progress of the investigative effort. The report shall be prepared in consultation with the RCT and submitted by the RCT through the IFS for compilation and presentation to the Council at a Council meeting. Form FDLE/IFS-004, Violent Crime and Drug Control Council Bi-Annual Report, revised 10/01/08, incorporated by reference, shall be utilized to make the report. In addition, the Council may require oral progress reports to be made at Council meetings by a representative of the RCT or a designee of the lead investigative agency in a funded investigative effort.

(b) Agencies receiving Council funding shall retain documentation supporting the amounts and purposes of expenditures made from Council funds, the performance and accomplishments of the investigative efforts, and shall make these available to the Council upon request. With regard to agency personnel assigned to investigative efforts receiving Council funds, each agency shall retain, and make available to the Council as requested, each employee's official time and leave records and such other documentation demonstrating the time devoted by the employee to the funded investigative effort, but these records shall not be submitted with Form FDLE/IFS-004.

(c) Agencies receiving Council funding shall provide such other information as required by the Council or the IFS in its capacity as support staff, to assist in preparing its annual report to the Legislature, to assist audits of Council activities, or to assist the Council and IFS in fulfilling their role to monitor the performance of funded investigations.

(17) If funds provided by the Council remain unexpended upon the conclusion of any investigative effort, the participating agencies shall return unexpended Council funds to the Council within 90 days of the conclusion of the investigative effort.

(18) If an agency receiving Council funds is subsequently reimbursed or funded from another source of funding for the expenditures funded by the Council, the receiving agency shall return to the Council an amount that is the lesser of the subsequent reimbursement or the funding received from the Council.

(19) If agencies receiving Council funding fail to submit the required Form FDLE/IFS-004, by the stated deadline, the Council Chairperson in consultation with FDLE/IFS staff is authorized to demand that all unexpended funds be returned within 30 days. Upon such a finding, the Agency Head of the funded agencies will be notified in writing as to the manner in which such funds must be returned. Any agency that is delinquent in submitting Form FDLE/IFS-004 by 90 or more days shall be subject to this provision.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New _____.

11N-1.006 Contributions.

Local law enforcement agencies or other entities may contribute to the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account by submitting funds to the executive director of the Department of Law Enforcement. Contributions should be accompanied by a written statement designating the funds to the Violent Crime Investigative Emergency and Drug Control Strategy Implementation Account. Agencies receiving forfeiture proceeds by reason of an investigative effort receiving Council funds may contribute a portion of those proceeds to the Department of Law Enforcement for use by the Council in further funding efforts.

Specific Authority 943.03(4), 943.042 FS. Law Implemented 943.031, 943.042 FS. History–New 3-10-94, Amended 10-10-95, 10-25-01, 3-27-06, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Joyce Gainous-Harris

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Governor and Cabinet

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 17, 2008

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

Notices for the Board of Trustees of the Internal Improvement Trust Fund between December 28, 2001 and June 30, 2006, go to http://www.dep.state.fl.us/ under the link or button titled "Official Notices."

WATER MANAGEMENT DISTRICTS

South Florida Water Management District

RULE NOS.:	RULE TITLES:
40E-2.011	Policy and Purpose
40E-2.091	Publications Incorporated by Reference
40E-2.301	Conditions for Issuance of Permits
40E-2.331	Modification of Permits

PURPOSE AND EFFECT: To incorporate requirements for protecting reserved water pursuant to Section 373.223(4), F.S. and to establish a water reservation for the Picayune Strand and Fakahatchee Estuary.

SUMMARY: The District proposes to amend the conditions for issuance of an individual water use permit to include a condition that the proposed use does not withdraw reserved water. The District also proposes to add a requirement to the section on Modification of Permits that reserved water may not be withdrawn. In addition, the proposed amendments to the Basis of Review for Water Use Permit Applications within the South Florida Water Management District set forth the criteria for establishing reasonable assurances that reserved water is not withdrawn upon issuance of a consumptive use permit. The criteria provide for one exception – the withdrawal of water less than 100,000 gallons per day associated with public access/recreational or land management activities. A definition section with key terms has also been included. The proposed amendments set forth eight categories of consumptive uses that do not withdraw reserved water. If a consumptive use does not fall into one of these categories, the applicant must undertake modeling following the specific requirements set forth in the proposed criteria or other similarly acceptable alternative modeling evaluations to demonstrate that reserved water is not being withdrawn. Finally, the criteria provide that reduced or terminated permit impacts that result in increased inflows into the reservation water body may be allocated unless the Governing Board of the South Florida Water Management District determines that such allocation is inconsistent with the public interest.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS:

Individuals and Entities Affected by the Proposed Rule

The proposed rule reserves water for protection of fish and wildlife in the Picayune Strand and the Fakahatchee Estuary in Collier County. The proposed rule will affect a subset of individuals and entities requesting water allocations from surface waters, the water table aquifer or the minimally confined portions of the lower Tamiami aquifer in western Collier County.

Water use permit applications proposing to withdraw waters that are reserved for the Picayune Strand or the Fakahatchee Estuary under the proposed rule would be denied. In this case, the applicant may choose to switch locations of water withdrawals to deeper portions of the subsurface within the aquifers not affected by the rule, reduce the proposed withdrawal, or move the proposed withdraw location farther away from the reservation water body or impacted canal. The number of individuals and entities potentially affected by this rule is not known but could include public supply utilities, industry, agricultural firms, golf course owners and entities that wish to maintain landscaping such as parks and schools located near the reservation water bodies or specified tributaries that deliver surface water that is proposed to be reserved under the rule. The geographic area affected by the proposed rule is limited to western Collier County. Existing land uses (platted single family homes, agricultural land holdings and publicly owned conservation lands) act to limit access to the surface waters within the reservation water bodies and canals where inflows are reserved.

The proposed rule set forth eight categories of consumptive uses that do not withdraw reserved water. If a consumptive use does not fall into one of these categories, the applicant must undertake modeling following the specific requirements set forth in the proposed criteria or other similarly acceptable alternative modeling evaluations to demonstrate that reserved water is not being withdrawn. Finally, the criteria provide that reduced or terminated permit impacts that result in increased inflows into the reservation water body may be allocated unless the Governing Board of the South Florida Water Management District determines that such allocation is inconsistent with the public interest.

Transactional Costs

A summary of the transactional costs is as follows.

• Existing legal uses on the effective date of the rule will have no transactional costs.

• Applicants for renewal of existing legal water uses on the effective date of the rule will have no transactional costs.

• New or modified uses that are not direct or indirect withdrawals will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

• Permit modifications that do not change the source, increase the allocation, or change withdrawal locations will have no transactional costs.

• Applicants for withdrawals from the Sandstone aquifer, Mid-hawthorn aquifer or the Floridan Aquifer systems will have no transactional costs.

• A proposed new use with a direct or indirect withdrawal and no greater impact, including changes in timing, on a reservation water body than the terminated or reduced permit existing on [effective date] within the same project site will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

Costs of Modelling under Section 3.11.1.B.

An integrated surface and ground water transient model (transient hydrologic model) must be developed, calibrated and run for permit applications that are determined to have the potential of withdrawing reserved water quantities. Pursuant to Subsection 3.11.1.A.8., this group only includes applications for new or modified permits that have a direct or indirect withdrawal, as defined in the proposed rule.

This integrated transient hydrologic modeling is estimated to cost between $100,000 to $500,000, depending on the amount of data collection and modeling needed to determine whether the requested allocation will withdraw reserved water. The higher range of costs are associated with developing a model from scratch including developing regionalized input data sets for all model parameters. The lower range of costs consider time and cost savings associated with using existing regionalized input data sets when assembling a model. The District has developed two calibrated integrated transient models for the area (Picayune Strand PIR model and the LWC SAS Sub-Regional model). The input data sets are available to the public as public records and may be used by permit applicants in the development of the modeling required pursuant to the reservation rule.

If the results of the hydrologic modeling indicate that proposed new or modified withdrawals will withdrawal reserved water, the applicant may choose to develop an alternative water source, or otherwise modify the project so no reserved water will be withdrawn. The likely alternatives include aquifers located beneath the Lower Tamiami aquifer as specified in the rule. These include, in descending order, the Sandstone, Hawthorn Zone I / Lower Hawthorn, and Floridan aquifers.

For non-potable water uses, moving from a surface water source to the confined Lower Tamiami aquifer or the Sandstone aquifer will increase water supply costs by about $0.10 per 1,000 gallons of water produced. There is no significant cost difference between obtaining fresh water from the Water Table aquifer, the lower Tamiami aquifer, or the Sandstone aquifer. However, if these applicants are not able to obtain water from these sources, the increased cost associated with pumping and treating brackish water from the Hawthorn aquifer or the Floridan aquifer will increase significantly. The cost increase associated with going from the water table, lower Tamiami or Sandstone with not treatment to the Floridan Aquifer System with reverse osmosis treatment ranges from $3.42 per 1,000 gallons of water produced to $3.62 per 1,000 gallons depending on which aquifer is used.

For a public supply utility, the cost increase is not significant if the applicant moves from the Water Table aquifer or the Lower Tamiami aquifer to the Sandstone aquifer. However, if the applicant uses the Hawthorn or the Floridan aquifers, the cost increases by about $0.60 to $0.70 per 1,000 gallons. In this case, the degree of financial and economic impacts to the public supply utility would depend on the proportion of the utility's total water supply that comes from these sources.

Applicants for dewatering projects which retain the effluent water on-site, will not be impacted by the rule. If the retaining water on site is not feasible, the applicant will be required to demonstrate reserved water is not withdrawn. This could be done through modeling, or modifying the project (e.g. construction in the wet, establishing a hydraulic barrier between the dewatering site and the reservation water body, phased dewatering to reduce the impact e.t.c.). No specific cost estimates of these options have been compiled.

Cost to the District

The estimated one-time cost to the District to implement the proposed rule is $16,200. The estimated cost to the District to address each water use permit application that occurs within the area affected by this rule could be as much as $4,800 to $5,700 per applicant and $2,100 per dewatering permit for projects that involve extensive review. However, those projects that do not involve significant evaluations (such as renewals, modifications not involving reserved water, projects using alternative sources of supply etc.) will have minimal costs to the District.

Cost to Small Businesses, Small Cities and Small Counties

The City of Everglades will be affected by the proposed rule if it requests additional permitted water quantities from surface water or from the water table aquifer or from the lower Tamiami aquifer in western Collier County. There are likely to be several small businesses in Collier County that could be developed within the geographic area influenced by the rule. The potential costs associated with this rule are tied to the volume of water needed for the business, the location of the withdrawal, and the level of treatment needed.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 373.044, 373.113, 373.118, 373.171 FS.

LAW IMPLEMENTED: 373.036, 373.042, 373.0421, 373.103(1), 373.103(4), 373.109, 373.1501, 373.1502, 373.196, 373.203, 373.216, 373.219, 373.223, 373.224, 373.229, 373.2295, 373.232, 373.233, 373.236, 373.239, 373.249, 373.250, 373.470 FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: February 12, 2009, 9:00 a.m.

PLACE: South Florida Water Management District, B-1 Auditorium, 3301 Gun Club Road, West Palm Beach, FL 33406

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: South Florida Water Management District Clerk, (800)432-2045, ext. 2087 or (561)682-2087. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Scott Burns, Director, Everglades Water Supply Policy, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4224 or (561)682-4224, email: sburns@sfwmd.gov; Brenda Mills, Lead Planner, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4208 or (561)682-4208, email: bmills@sfwmd.gov; Beth Lewis, Senior Supervising Attorney, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6343 or (561)682-6343, email: belewis@sfwmd.gov. For procedural questions contact Jan Sluth, Senior Paralegal, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6299 or (561)682-6299, email: jsluth@sfwmd.gov

THE FULL TEXT OF THE PROPOSED RULES IS:

40E-2.011 Policy and Purpose.

(1) through (2) No change.

(3) Additional rules relating to water use are found in Chapter 40E-5, F.A.C., (Artificial Recharge), Chapter 40E-8, F.A.C., (Minimum Flows and Levels), Chapter 40E-10, F.A.C., (Water Reservations), Chapters 40E-20, F.A.C., (General Water Use Permits), 40E-21, F.A.C., (The Water Shortage Plan), 40E-22, F.A.C., (Regional Water Shortage Plans) and 40E-23, F.A.C., (Water Resource Caution Areas).

(4) No change.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.103(1), 373.203, 373.216, 373.249 FS. History–New 9-3-81, Formerly 16K-2.01, Amended 7-4-82, 2-24-85, 11-18-91, 8-1-02, 8-31-03, _____.

40E-2.091 Publications Incorporated by Reference.

The "Basis of Review for Water Use Permit Applications within the South Florida Water Management District – _____~~October 14, 2008~~", is hereby published by reference and incorporated into this chapter. A current version of this document is available upon request.

Specific Authority 373.044, 373.113, 373.118, 373.171 FS. Law Implemented 373.042, 373.0421, 373.109, 373.196, 373.219, 373.223, 373.224, 373.229, 373.232, 373.233, 373.236, 373.239, 373.250 FS. History–New 9-3-81, Formerly 16K-2.035(1), Amended 2-24-85, 11-21-89, 1-4-93, 4-20-94, 11-26-95, 7-11-96, 4-9-97, 12-10-97, 9-10-01, 12-19-01, 8-1-02, 6-9-03, 8-31-03, 4-23-07, 9-13-07, 2-13-08, 10-14-08, _____.

(The following changes are proposed to the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District")

1.7.5.2 Modeling Data

Applicable modeling data may consist of basic analytic impact assessments or calibrated numeric system simulation models. The modeling impact assessments shall be conducted for the proposed withdrawal alone, as well as the proposed withdrawal combined with all other permitted uses and pending applications within the cone of depression of the proposed use. The cone of depression is defined by the 0.1 foot drawdown contour for the proposed withdrawal from the water table aquifer and the 1.0 foot contour for the proposed withdrawal from a confined aquifer.

A. Basic analytic impact assessments: Basic analytic impact assessments utilize an approved analytic equation(s), such as the Theis or Hantush-Jacob equation, applied to the requested maximum month allocation that simulates continued withdrawal for 90 days without recharge (which is considered for purpose of these simulations to be equivalent to a 1 in 10 year drought condition). Aquifer characteristics derived from approved aquifer performance tests (APT) or specific capacity tests (SFWMD, Part B Water Use Management System Design and Evaluation Aids, Part II Aquifer Performance Test) located within one mile of the project site are acceptable. If more than one set of aquifer characteristics data exists within one mile of the site, the value measured closest to the proposed project will be used unless the applicant can demonstrate that hydrogeologic conditions at the project site are not represented by such data. If the location of the nearest site where aquifer characteristics were measured is greater than one mile from the project site, the average of the nearest three APT or specific capacity test sites is acceptable providing that two of the three values are within one standard deviation of the mean. If this is not the case, the applicant shall demonstrate that the conditions of permit issuance are met for the highest and lowest values of the three sites, or the applicant may opt to conduct an APT or specific capacity test at the site.

The use of numeric models such as Modflow without calibration is acceptable under the following configurations: (1) the model represents the aquifer or aquifer system as no more than two layers; (2) each layer uses a single value for transmissivity/permeability, storage/storativity and a single value is used for leakance between the layers; (3) the simulation time is 90 days with no recharge; and (4) surface water recharge features are not represented. The modeling shall include separate runs using the highest and lowest measured values of transmissivity/permeability, storage/ storativity, and leakance from the region, based on published data and pump test values calculated as described above. The selected high and low aquifer values will be approved provided they significantly overestimate the withdrawal impacts that would occur on the site. The use of a numeric model without calibration is acceptable for representing seepage irrigation systems where the applicant models the portion of the irrigation water that returns to the water table aquifer, provided the model is configured as described in this paragraph and the change in the water table elevation predicted by the model is field verified with water level data from at least one water table piezometer located adjacent to the irrigated field.

(Subsection 1.7.5.2 B. remains unchanged)

1.8 Definitions

Allocation Coefficient through Reclaimed Water – No change.

Reservation water body – Areas within the District as identified in Rules 40E-10.021 and 40E-10.041, F.A.C., for which a water reservation has been established.

Resource Efficiency through Xeriscape – No change.

2.5.2 Dewatering General Water Use Permit.

Dewatering General Water Use Permits, as described in subsection 40E-20.302(2), F.A.C., are for dewatering projects, which a) cannot meet the conditions of issuance and requirements for "No-Notice" permits, b) have a proposed duration of less than one year, and c) propose to pump less than 10 million gallons per day with a total project volume of less than 1800 million gallons. A dewatering general water use permit application must be submitted to the District and Staff must issue the General Permit prior to the applicant beginning dewatering, unless portions of the project qualify for dewatering under the "No-Notice" permit described above. The applicant may elect to begin dewatering for a single period of only 90 days in areas of the project, which meet the "No-Notice" criteria, once an application for a Dewatering General Water Use Permit has been submitted to the District.

Permit applications for a Dewatering General Water Use Permit must:

(1) through (4) No change.

(5) Demonstrate that reserved water will not be withdrawn pursuant to paragraph 40E-20.301(1)(k), F.A.C., by retaining all water onsite. If the Applicant demonstrates that retaining the water on site is not feasible, the application shall be processed as an individual permit pursuant to Section 2.5.3.

(6)~~(5)~~ Provide reasonable assurances that fresh dewatering water will not be discharged to saline tidal waters, unless the applicant demonstrates that it is not technically feasible to prevent discharge to saline water and requests specific authority from the District for discharge. Saline dewatering water, as defined in this Basis of Review, may be discharged to tidewater.

(7)~~(6)~~ Provide an operational plan which describes how stormwater will be handled during dewatering operations.

Dewatering applications will be reviewed concurrently with Environmental Resource or Surface Water Management construction permit applications, and the dewatering application will not be considered complete until both applications are complete. An applicant may request that the dewatering permit include a later "start" date to coincide with the actual start of dewatering activities at the project. Staff will recommend a permit expiration date, based on the proposed "start" date. Any temporary dewatering water holding areas must be constructed and operated using sound engineering practices to protect public health, safety, and welfare and, as necessary, dewatering activities must meet all applicable Environmental Resource or Surface Water Management criteria.

2.5.3 Long-Term Dewatering Individual Permits.

Long-term dewatering individual permits apply to projects that exceed the thresholds and criteria described in Sections 2.5.1 and 2.5.2 above. These permits must be approved by the District Governing Board. Two types of individual dewatering permits are available from the District. For projects where all the dewatering activities are defined at the time of the permit application, the applicant may apply for a "standard" Individual Permit. For long-term, multi-phased projects, with undefined activities or no contractor at the time of the permit application, the applicant may apply for a "master" Individual Permit.

Applicants for all individual dewatering permits must satisfy the conditions of issuance for Individual Permits (Rule 40E-2.301, F.A.C.), and may not commence dewatering prior to approval of the permit by the Governing Board. In order to provide reasonable assurances that water reserved in Rule 40E-10.041, F.A.C., will not be withdrawn, all water from the

dewatering activity shall be retained on site. If the applicant demonstrates that retaining the water on site is not feasible, the project shall be modified to demonstrate pursuant to Section 3.11 that reserved water will not be withdrawn. The applicant may elect to begin dewatering for a single period of only 90 days in areas of the project, that meet the No-Notice criteria specified in Section 2.5.1 of this Basis of Review, once an application for an Individual dewatering permit has been submitted to the District.

The applicant must provide the information required for the Dewatering General Permit, as specified in Section 2.5.2. In addition, the applicant shall provide estimates of the maximum monthly and annual dewatering withdrawals for the project and will be required to submit records of monthly withdrawals for each dewatering pump to the District. Staff shall not specify maximum monthly or annual withdrawal volumes in the recommended permit conditions presented to the Governing Board.

A. "Standard" Individual Permits

No change.

B. "Master" Individual Permits

No change.

3.11 Water Reservations.

3.11.1 Picayune Strand and Fakahatchee Estuary.

A permit applicant shall provide reasonable assurances that the proposed use will not withdraw water reserved under subsections 40E-10.041(1) and (2), F.A.C., except that water uses less than 100,000 gallons per day associated with land management or public access/recreation shall be permittable. Compliance with the following criteria constitutes reasonable assurances that water reserved in subsections 40E-10.041(1) and (2), F.A.C., will not be withdrawn. Water not reserved under subsections 40E-10.041(1) and (2), F.A.C., shall be allocated pursuant to subsections A and B.

For this section, the following definitions apply:

Direct Withdrawals from Groundwater: Water pumped from a well(s) constructed within the boundaries of the Picayune Strand or Fakahatchee Estuary into the water table or unconfined portions of the Lower Tamiami aquifer.

Indirect Withdrawals from Groundwater: a) a groundwater withdrawal from a well(s) constructed outside the boundaries of Picayune Strand and Fakahatchee Estuary into the water table or Lower Tamiami aquifer that results in a 0.1 foot or greater drawdown in the water table aquifer at any location underlying the Picayune Strand or the Fakahatchee Estuary, as determined by an evaluation conducted pursuant to Section 1.7.5.2.A.; or b) a groundwater withdrawal that causes a water table drawdown of 0.1 foot or greater underlying any canal identified in Figure 3-5, as determined by an evaluation conducted pursuant to Section 1.7.5.2.A.

Direct Withdrawals from Surface Water: Withdrawal of surface water from facilities physically located within the Picayune Strand or Fakahatchee Estuary boundaries.

Indirect Withdrawal from Surface Water: Withdrawal of surface water from any canal identified in Figure 3-5.

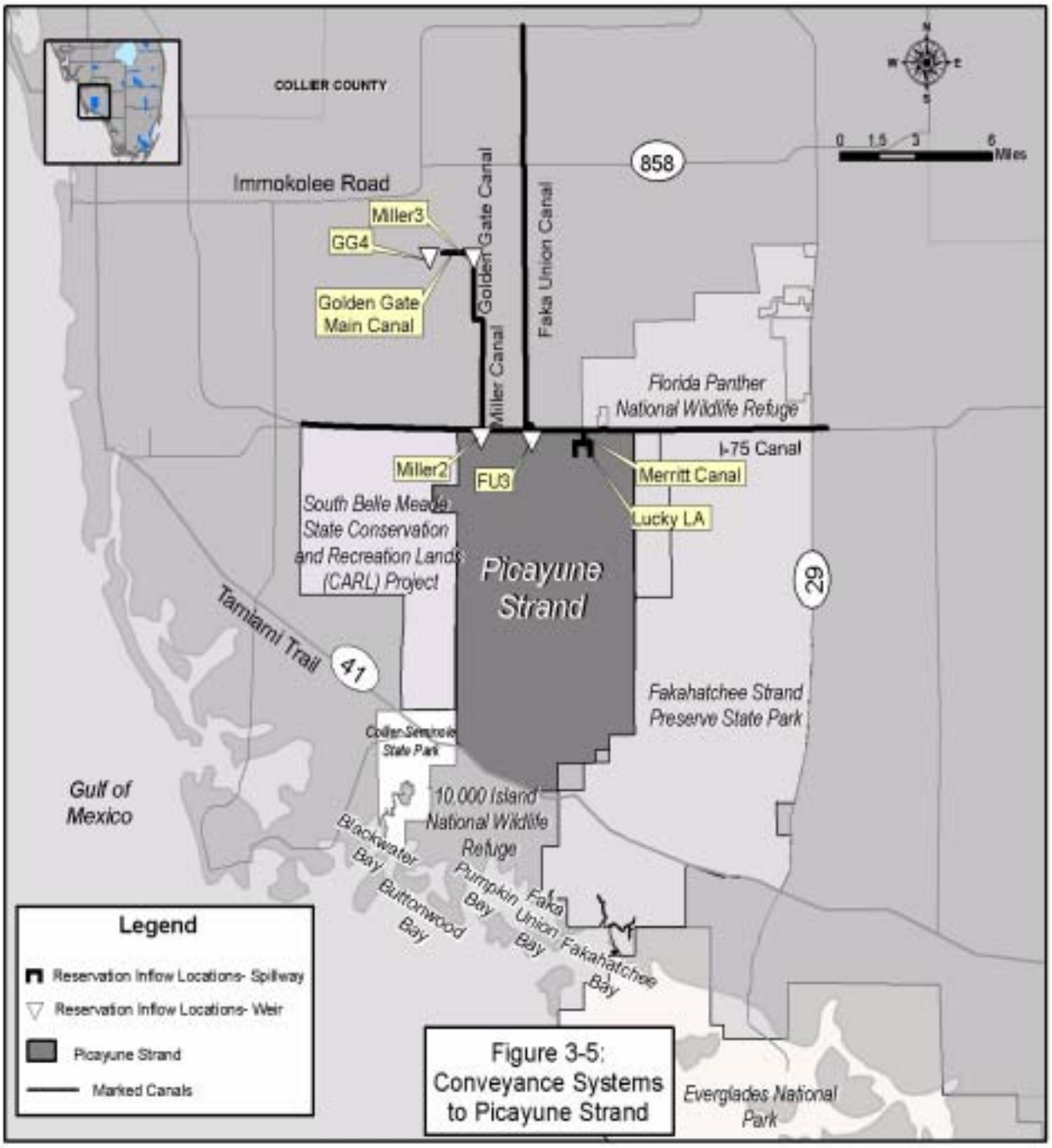


Figure 3-5: Conveyance Systems to Picayune Strand

A. The following uses do not withdraw reserved water:

1. Withdrawals from the Sandstone aquifer, Mid-Hawthorn aquifer or the Floridan Aquifer Systems;

2. Withdrawals authorized by subsection 40E-20.302(3), F.A.C. (No-Notice Short-Term Dewatering General Water Use Permit);

3. A renewal of a water use authorized by a permit existing on [effective date]. If the level of certainty under the permit being renewed is changed to a 1 in 10 year level of certainty pursuant to Section 2.3.2 (e.g. a golf course irrigation level of certainty changed from a 1 in 5 to a 1 in 10 year level of drought), the resulting 1 in 10 year allocation shall be authorized;

4. A permit modification that does not change the source, increase the allocation or change withdrawal locations, such as replacement of existing wells with similar construction and at similar locations, crop changes that do not change the allocation or timing of use, or decrease in allocation;

5. A permit modification that does not result in a direct or indirect withdrawal as demonstrated through an analysis conducted consistent with Section 1.7.5.2.A. When a modification to an existing permit is requested, the 0.1 foot threshold for determining a direct or indirect withdrawal will be applied to the effect of the modification only. The change in the drawdown solely associated with the applicant's proposed modification is calculated at the location of the 0.1 foot drawdown contour associated with the existing permit. If the change in drawdown associated with the proposed modification is less than 0.1 foot, the applicant's modification does not withdraw reserved water;

6. A proposed new use that does not result in a direct or indirect withdrawal as demonstrated through an analysis conducted pursuant to Section 1.7.5.2.A.

7. A proposed new use with a direct or indirect withdrawal and no greater impact, including changes in timing, on a reservation water body than the terminated or reduced permit existing on [effective date] within the same project site. This evaluation will be conducted pursuant to Section 1.7.5.2.

8. A proposed new use or proposed modification of a permit with an indirect withdrawal that does not withdraw reserved water from the Picayune Strand or the Fakahatchee Estuary. The determination that reserved water is not withdrawn shall be demonstrated by conducting the Model Impact Evaluation in Section B.

B. Model Impact Evaluation. If required by Section A, the applicant shall demonstrate water reserved for the Picayune Strand and Fakahatchee Estuary will not be withdrawn by conducting the following Model Impact Evaluation. A pre-application meeting between the Applicant and District staff is strongly recommended to be conducted prior to initiating model development.

1. Defining Scope of Model Evaluation.

(a) For groundwater withdrawals, identify the cone of influence of the proposed withdrawal per Section 1.7.5.2.A. Based on this analysis, the Applicant shall identify which reservation inflow locations (set forth in Figures 1 and 2 in Rule 40E-10.021, F.A.C.) and conveyance system(s) identified on Figure 3-5 are potentially influenced by the proposed withdrawal.

(b) For surface water withdrawals, identify the reservation inflow locations, reservation water body (set forth in Figures 1 and 2 in Rule 40E-10.021, F.A.C.), and conveyance system(s) identified on Figure 3-5 that are potentially influenced by the proposed withdrawal.

2. Conditions of Model Development.(a) Boundary Conditions: The model domain and resolution of grid cell size shall be identified using professional standards for model development considering the area of influence, while avoiding boundary condition biases. At a minimum, boundaries shall be situated sufficiently distant from the area of interest or in such a manner as to prevent non-representative impacts from specified boundary conditions on predicted stages and/or flow in the area of interest.

(b) Surface and groundwater interactions: Surface and groundwater model codes that have undergone professional peer review and are representative of the physical system being simulated shall be used. Where integrated surface water and groundwater models are applied, time steps will be selected with consideration given to the resolution of the available data and the resolution necessary for quantifying flow volumes. Surface waters and overland flow time steps not exceeding 4 hours in length, canal flows time steps not exceeding 3 minutes, and groundwater time steps not exceeding 6 hours in length shall be considered acceptable. Alternative time steps may be used providing they produce an acceptable calibration as described in Subsection 3.11.1B.2(f). For the purposes of model calibration, the time steps used for simulating stages shall be averaged and flows shall be summed to produce daily values for comparison to measured data.

(c) Hydrologic Conditions: Rainfall and evapotranspiration shall be simulated based on data collected from 1988 through 2000 for the model domain.

(d) Land Use/Water Use: The model shall simulate 2000 land use existing on December 31, 2000 within the model domain (as identified in paragraph (a), above). The water use withdrawal data used for the model calibration shall reflect actual use during the period of 1988 through 2000. In the case of irrigation type uses, a supplemental crop irrigation module from the model code selected per paragraph (b) shall be acceptable for calculating variable demands.

(e) Project Features and Operations: Model simulations shall include project features and operations of the Picayune Strand Restoration Project utilized to simulate the flows identified in Rule 40E-10.041, F.A.C.

(f) Model Calibration: To calibrate the model, the model output shall be compared to the affected flow probability distribution(s) in Rule 40E-10.041, F.A.C., and surface water, groundwater stage, and flow data from monitoring sites located within the model domain. The model shall be considered calibrated when surface water and groundwater stage and flow are calibrated as required by subsections (i), (ii) and (iii), below, and the resulting flow probability distribution curves from the Applicant's model are consistent with the magnitude and timing of flows in the flow probability distribution curves identified in Rule 40E-10.041, F.A.C., for the time period including 1988 through 2000. In the event that the simulated model output for a monitoring site(s) or the flow probability distribution(s) does not meet these criteria, the Applicant shall provide a justification of the deviation. If such justification adheres to documented physical conditions in the field and comports with professionally accepted principles of hydrology, the monitoring sites or flow probability distribution(s) that do not meet the criteria shall be accepted.

i. Groundwater Stage Data: The mean error determined by comparing the model calculated groundwater stage as described in Subsection 3.11.1.B.2.(b) with the corresponding measured data shall not exceed 1.0 foot for the time period including January 1, 1995 through December 31, 1999. If the mean error is exceeded at a monitoring location, the groundwater calibration shall be considered acceptable when the absolute mean error of all the groundwater monitoring locations within the model domain do not exceed 1.0 foot and the deviation between the model simulation value and the measured value is explained as set forth in Subsection 3.11.1.B.2.(f).

ii. Canal Stage Data: The average mean error determined by comparing the model simulated surface water stages as described in Subsection 3.11.1.B.2.(b) with the corresponding measured data should not exceed 0.3 foot for the time period including January 1, 1995 through December 31, 1999.

iii. Flow Data: The mean error determined by comparing the model simulated surface water flow as described in Subsection 3.11.1.B.2.(b) with the corresponding measured data shall not exceed ten percent for the time period including January 1, 1995 through December 31, 1999.

3. Impact Evaluation.

Once the model is calibrated, Applicants shall demonstrate that water reserved for the Picayune Strand and Fakahatchee Estuary will not be withdrawn, based on the following:

(a) "Without scenario": All existing legal uses at the effective date of the rule shall be represented using the allocation in the permit. For the purposes of this evaluation and subsection (b), the annual allocation shall be distributed on a monthly basis based on the use type. For a public water supply use type, the monthly distribution shall be calculated based on the measured monthly pumpage divided by the annual total pumpage using the average of the three most recent representative years. Representative years shall not include years with water shortage restrictions, years with plant failures or other years that are not representative of normal pumpage. For an irrigation use type, the monthly distribution shall be determined using the Blaney-Criddle distribution calculated for each project per "Part B Water Use Management System Design and Evaluation Aids." The annual allocation and the associated monthly distribution shall be simulated using the calibrated model developed in accordance with the criteria identified in Subsection 3.11.1.B.2 in order to generate a daily flow data for each represented inflow location identified in Subsection 3.11.1. These data shall be presented as daily hydrographs as well as seasonal and period of record flow probability curves.

(b) "With Scenario": The "with scenario" includes all existing legal uses at the time of the evaluation of the application and the proposed use and pending applications for which the evaluation under this subsection is being conducted. The annual allocation and the associated monthly distribution shall be simulated using the calibrated model developed in accordance with the criteria identified in Subsection 3.11.1.B.2 in order to generate a daily flow data for each represented inflow location identified in Subsection 3.11.1. These data shall be presented as daily hydrographs as well as seasonal and period of record flow probability curves.

(c) The resulting flow volume distributions of the "with" and "without" scenarios shall be compared to determine whether the proposed use withdraws reserved water. Withdrawals of reserved water occur when the simulated flow volume probability curve(s) of the "with scenario" differs in flow distribution when compared to the "without scenario" at any of the inflow locations identified in Subsection 3.11.1.B.1.

4. Alternative Model Evaluations.

Applicants may propose alternative modeling evaluations in order to provide reasonable assurances that the proposed project does not withdraw water reserved under Rule 40E-10.041, F.A.C. Such modeling shall evaluate the impacts of the proposed project on the reservation water body under a representative range of hydrologic conditions for which the water reservations have been established (e.g. wet, average, dry hydrologic conditions). Proposed alternative modeling evaluations shall be submitted in writing to the District for review and comment prior to conducting such modeling either in a pre-application meeting or as part of the permit application. District staff shall approve those model approaches which utilize documented model codes that have undergone professional peer review and accurately represent the physical system; are calibrated consistent with the criteria contained in Subsection 3.11.1.B.2(f)i., ii., and iii. or other appropriate criteria; accurately represents impacts to inflows of reserved water into the reservation water body as described in Rule 40E-10.041, F.A.C.; and represents existing legal uses and the proposed project withdrawals.

5. Reduced or Terminated Permit Impacts.

If an existing legal use at the effective date of the rule has been reduced or terminated and results in increased inflows that result from the reduced or terminated use into the reservation water body, the applicant may seek an allocation that withdraws such increased inflows at any of the inflow locations identified in Subsection 3.11.1.B.1. provided that the waters reserved in Rule 40E-10.041, F.A.C. are not reduced as demonstrated through an analysis conducted pursuant to Subsection 3.11.1.B.3. or 4. The quantity of increased inflow shall be available for allocation unless the Governing Board determines that allocation of the water is not consistent with the public interest under Section 373.223(1)(c), F.S.

In the event these criteria cannot be met, the applicant shall modify the application to otherwise meet the requirements of this Section.

40E-2.301 Conditions for Issuance of Permits.

(1) (a) through (j) No change.

(k) Will not withdraw water reserved under Chapter 40E-10, F.A.C.

(2) No change.

Specific Authority 373.044, 373.113, 373.118 FS. Law Implemented 373.036, 373.042, 373.103(4), 373.1501, 373.1502, ~~373.118,~~ 373.223, 373.229, 373.2295, 373.470 FS. History–New 8-14-02, Amended 8-31-03, 4-23-07, 2-13-08,_____.

40E-2.331 Modification of Permits.

(1) through (3) No change.

(4)(a) Modification of an existing water use permit shall be approved by letter, provided the permit is in compliance with all applicable limiting conditions and the modification request:

1. Does not result in an increase in the amount of the permit allocation;

2. Does not modify the existing permit expiration date, except that when the permit duration is based upon the current lease expiration date, the permit duration shall be extended by letter modification to the new lease date, but shall not exceed the applicable permit duration pursuant to Rule 40E-2.321, F.A.C.;

3. Does not potentially interfere with any presently existing legal use of water, cause environmental harm, saltwater intrusion, pollution of the water resources, harm to offsite land uses, does not withdraw water reserved under Chapter 40E-10, F.A.C., or does not otherwise raise issues requiring a Staff determination of whether such impacts would occur pursuant to the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District", incorporated by reference in Rule 40E-2.091, F.A.C.; and

4. Does not change the permitted withdrawal source(s) or use classification.

5. Does not result in a modification of the permit which must be approved by the Governing Board pursuant to Section 373.239(2), F.S.

(b) No change.

Specific Authority 373.044, 373.113 FS. Law Implemented 373.223, 373.229, 373.239 FS. History–New 9-3-81, Formerly 16K-2.09(1), Amended 4-20-94, 7-11-96, 4-9-97, 12-10-97, 8-1-02, 4-23-07, 2-13-08,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Wm. Scott Burns, Director, Everglades Water Supply Policy Implementation

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: South Florida Water Management District Governing Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 2, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 3, 2008

WATER MANAGEMENT DISTRICTS

South Florida Water Management District

RULE NOS.:	RULE TITLES:
40E-10.011	Purpose and General Provisions
40E-10.021	Definitions
40E-10.031	Water Reservations
40E-10.041	Water Reservation Areas: Lower West Coast Planning Area

PURPOSE AND EFFECT: To define the quantity, location and timing of waters reserved from allocation for the protection of fish and wildlife pursuant to Section 373.223(4), F.S., for specified water bodies.

SUMMARY: This chapter establishes both surface water and groundwater reservations for the Picayune Strand and the Fakahatchee Estuary. These reservations are based on information contained in the peer reviewed report entitled "Technical Document to Support a Water Reservation Rule for Picayune Strand and Downstream Estuaries", which establishes the linkages between the identification of the reserved water and the protection of fish and wildlife. Because the water reservation authority under Section 373.223(4), F.S., authorizes the set aside of water from consumptive use, Chapter 40E-10, F.A.C. establishes that applicants for consumptive use permits meet the requirement of this chapter by providing reasonable assurances that criteria contained in rules governing issuance of individual and general water use permits are met. It also sets forth that presently existing legal uses for the duration of the permit existing on [effective date] are determined to be not contrary to the public interest, pursuant to Section 373.223(4), F.S. Finally, Chapter 40E-10, F.A.C. contains figures showing the location of the reserved water and the volume probability curves which simulated the surface water inflow that is protected by this Chapter.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: Individuals and Entities Affected by the Proposed Rule

The proposed rule reserves water for protection of fish and wildlife in the Picayune Strand and the Fakahatchee Estuary in Collier County. The proposed rule will affect a subset of individuals and entities requesting water allocations from surface waters, the water table aquifer or the minimally confined portions of the lower Tamiami aquifer in western Collier County.

Water use permit applications proposing to withdraw waters that are reserved for the Picayune Strand or the Fakahatchee Estuary under the proposed rule would be denied. In this case, the applicant may choose to switch locations of water withdrawals to deeper portions of the subsurface within the aquifers not affected by the rule, reduce the proposed withdrawal, or move the proposed withdraw location farther away from the reservation water body or impacted canal. The number of individuals and entities potentially affected by this rule is not known but could include public supply utilities, industry, agricultural firms, golf course owners and entities that wish to maintain landscaping such as parks and schools located near the reservation water bodies or specified tributaries that deliver surface water that is proposed to be reserved under the rule. The geographic area affected by the proposed rule is limited to western Collier County. Existing land uses (platted single family homes, agricultural land holdings and publicly owned conservation lands) act to limit access to the surface waters within the reservation water bodies and canals where inflows are reserved.

The proposed rule set forth eight categories of consumptive uses that do not withdraw reserved water. If a consumptive use does not fall into one of these categories, the applicant must undertake modeling following the specific requirements set forth in the proposed criteria or other similarly acceptable alternative modeling evaluations to demonstrate that reserved water is not being withdrawn. Finally, the criteria provide that reduced or terminated permit impacts that result in increased inflows into the reservation water body may be allocated unless the Governing Board of the South Florida Water Management District determines that such allocation is inconsistent with the public interest.

Transactional Costs

A summary of the transactional costs is as follows.

• Existing legal uses on the effective date of the rule will have no transactional costs.

• Applicants for renewal of existing legal water uses on the effective date of the rule will have no transactional costs.

• New or modified uses that are not direct or indirect withdrawals will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

• Permit modifications that do not change the source, increase the allocation, or change withdrawal locations will have no transactional costs.

• Applicants for withdrawals from the Sandstone aquifer, Mid-hawthorn aquifer or the Floridan Aquifer systems will have no transactional costs.

• A proposed new use with a direct or indirect withdrawal and no greater impact, including changes in timing, on a reservation water body than the terminated or reduced permit existing on [effective date] within the same project site will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

Costs of Modelling under Section 3.11.1.B.

An integrated surface and ground water transient model (transient hydrologic model) must be developed, calibrated and run for permit applications that are determined to have the potential of withdrawing reserved water quantities. Pursuant to Subsection 3.11.1.A.8., this group only includes applications for new or modified permits that have a direct or indirect withdrawal, as defined in the proposed rule.

This integrated transient hydrologic modeling is estimated to cost between $100,000 to $500,000, depending on the amount of data collection and modeling needed to determine whether the requested allocation will withdraw reserved water. The higher range of costs are associated with developing a model from scratch including developing regionalized input data sets for all model parameters. The lower range of costs consider time and cost savings associated with using existing regionalized input data sets when assembling a model. The District has developed two calibrated integrated transient models for the area (Picayune Strand PIR model and the LWC SAS Sub-Regional model). The input data sets are available to the public as public records and may be used by permit applicants in the development of the modeling required pursuant to the reservation rule.

If the results of the hydrologic modeling indicate that proposed new or modified withdrawals will withdrawal reserved water, the applicant may choose to develop an alternative water source, or otherwise modify the project so no reserved water will be withdrawn. The likely alternatives include aquifers located beneath the Lower Tamiami aquifer as specified in the rule. These include, in descending order, the Sandstone, Hawthorn Zone I / Lower Hawthorn, and Floridan aquifers.

For non-potable water uses, moving from a surface water source to the confined Lower Tamiami aquifer or the Sandstone aquifer will increase water supply costs by about $0.10 per 1,000 gallons of water produced. There is no

significant cost difference between obtaining fresh water from the Water Table aquifer, the lower Tamiami aquifer, or the Sandstone aquifer. However, if these applicants are not able to obtain water from these sources, the increased cost associated with pumping and treating brackish water from the Hawthorn aquifer or the Floridan aquifer will increase significantly. The cost increase associated with going from the water table, lower Tamiami or Sandstone with not treatment to the Floridan Aquifer System with reverse osmosis treatment ranges from $3.42 per 1,000 gallons of water produced to $3.62 per 1,000 gallons depending on which aquifer is used.

For a public supply utility, the cost increase is not significant if the applicant moves from the Water Table aquifer or the Lower Tamiami aquifer to the Sandstone aquifer. However, if the applicant uses the Hawthorn or the Floridan aquifers, the cost increases by about $0.60 to $0.70 per 1,000 gallons. In this case, the degree of financial and economic impacts to the public supply utility would depend on the proportion of the utility's total water supply that comes from these sources.

Applicants for dewatering projects which retain the effluent water on-site, will not be impacted by the rule. If the retaining water on site is not feasible, the applicant will be required to demonstrate reserved water is not withdrawn. This could be done through modeling, or modifying the project (e.g. construction in the wet, establishing a hydraulic barrier between the dewatering site and the reservation water body, phased dewatering to reduce the impact e.t.c.). No specific cost estimates of these options have been compiled.

Cost to the District

The estimated one-time cost to the District to implement the proposed rule is $16,200. The estimated cost to the District to address each water use permit application that occurs within the area affected by this rule could be as much as $4,800 to $5,700 per applicant and $2,100 per dewatering permit for projects that involve extensive review. However, those projects that do not involve significant evaluations (such as renewals, modifications not involving reserved water, projects using alternative sources of supply etc.) will have minimal costs to the District.

Cost to Small Businesses, Small Cities and Small Counties

The City of Everglades will be affected by the proposed rule if it requests additional permitted water quantities from surface water or from the water table aquifer or from the lower Tamiami aquifer in western Collier County. There are likely to be several small businesses in Collier County that could be developed within the geographic area influenced by the rule. The potential costs associated with this rule are tied to the volume of water needed for the business, the location of the withdrawal, and the level of treatment needed.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 373.044, 373.113, 373.171 FS.

LAW IMPLEMENTED: 373.016, 373.1501, 373.1502, 373.026, 373.219, 373.223, 373.4592, 373.4595, 373.470 FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: February 12, 2009, 9:00 a.m.

PLACE: South Florida Water Management District, 3301 Gun Club Road, West Palm Beach, FL 33406

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: South Florida Water Management District Clerk (800)432-2045, ext. 2087 or (561)682-2087. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Scott Burns, Director, Everglades Water Supply Policy, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4224 or (561)682-4224, email: sburns@sfwmd.gov; Brenda Mills, Lead Planner, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4208 or (561)682-4208, email: bmills@sfwmd.gov; Beth Lewis, Senior Supervising Attorney, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6343 or (561)682-6343, email: belewis@sfwmd.gov. For procedural questions contact Jan Sluth, Senior Paralegal, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6299 or (561)682-6299, email: jsluth@sfwmd.gov.

THE FULL TEXT OF THE PROPOSED RULES IS:

40E-10.011 Policy and Purpose.

The purpose of this Chapter is to define the quantity, location and timing of waters reserved from allocation for the protection of fish and wildlife pursuant to Section 373.223(4), F.S., for specified water bodies. Water reservations are implemented in the water use program pursuant to Chapters 40E-2 and 40E-20, F.A.C.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.016, 373.026, 373.036, 373.1501, 373.1502, 373.219, 373.223, 373.4592, 373.4595, 373.470 FS. History–New _____.

40E-10.021 Definitions.

(1) Fakahatchee Estuary – The area within the Ten Thousand Islands region including the following river/bay systems, from west to east: Blackwater River/Blackwater Bay, Whitney River/Buttonwood Bay, Pumpkin River/Pumpkin

Bay, Wood River, Little Wood River and Faka Union Canal/Faka Union Bay, and Fakahatchee Bay as depicted in Figure 2 Fakahatchee Estuary.

(2) Picayune Strand – The area located southwest of the Florida Panther National Wildlife Refuge, north of the Ten Thousand Islands NWR, east of the South Belle Meade State Conservation and Recreation Lands (CARL) Project, west of the Fakahatchee Strand Preserve State Park, and northeast of Collier-Seminole State Park as depicted in Figure 1 Picayune Strand. The legal description of the Picayune Strand is contained in Appendix 1.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.016, 373.026, 373.036, 373.1501, 373.1502, 373.219, 373.223, 373.4592, 373.4595, 373.470 FS. History–New _____.

40E-10.031 Water Reservations.

(1) Applicants for consumptive use permits shall meet the requirements of this rule by providing reasonable assurances paragraphs 40E-2.301(1)(k) and 40E-20.301(1)(k), F.A.C., and Section 3.11 of the Basis of Review for Water Use Permit Applications within the South Florida Water Management District are met.

(2) Reservations contained in Rule 40E-10.041, F.A.C., shall be reviewed in light of changed conditions or new information by 2014.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.016, 373.026, 373.036, 373.1501, 373.1502, 373.219, 373.223, 373.4592, 373.4595, 373.470 FS. History–New _____.

40E-10.041 Water Reservation Areas: Lower West Coast Planning Area.

(1) Picayune Strand as defined in subsection 40E-10.021(2), F.A.C.:

(a) Surface waters:

1. All surface water contained within the Picayune Strand are reserved from allocation (see Figure 1).

2. All surface water flowing into the Picayune Strand identified below is reserved from allocation:

a. The surface water flows depicted on Figures 3. A, B, and C, simulated at weir 'Miller2' within the Miller Canal (see Figure 1);

b. The surface water flows depicted on Figures 4. A, B, and C, simulated at weir 'FU3' within the Faka Union Canal (see Figure 1); and

c. The surface water flows depicted on Figures 5. A, B and C simulated at spillway 'Lucky LA' within the Merritt Canal (see Figure 1).

(b) Groundwater: All groundwater in the water table and unconfined portions of Lower Tamiami aquifer underlying the Picayune Strand is reserved from allocation.

Notwithstanding the above, presently existing legal uses for the duration of the permit existing on [effective date] are determined to be not contrary to the public interest, pursuant to Section 373.223(4), F.S.

(2) Fakahatchee Estuary as defined in Rule 40E-10.021(1), F.A.C.:

(a) Surface waters:

The surface water flows into the Fakahatchee Estuary identified below are reserved from allocation:

1. The surface water flows depicted on Figures 6. A, B and C simulated at Faka Union Canal at structure FU1 (See Figure 2);

2. The surface water flows depicted on Figures 7. A, B and C simulated at 'Miller@41' transect (beginning at coordinate 471365.13N, 599423.29 E Southeast to 479226.67N, 595105.77E (delivering surface water to Blackwater Bay and Buttonwood Bay) see Figure 2);

3. The surface water flows depicted on Figures 8. A, B and C simulated at 'FU@41' transect (beginning at coordinate 480427.89N, 595005.67E Southeast to 487735.34N, 592478.09E (delivering surface water to Pumpkin Bay) see Figure 2);

4. The surface water flows depicted on Figures 9. A, B and C simulated at 'Merritt@41' transect (beginning at coordinate 490942.49N, 593218.49E flowing Southeast to 499050.54N, 590515.81E (delivering surface water to Faka Union Bay) see Figure 2); and

5. The surface water flows depicted on Figures 10. A, B and C simulated at 'Fakahatchee@41' transect (beginning at coordinate 498623.81N, 587955.37E Southeast to 533587.95N, 575807.53E (delivering surface water to Fakahatchee Bay) see Figure 2).

(b) Groundwater: All groundwater in the water table and unconfined portions of Lower Tamiami aquifer underlying the Fakahatchee Estuary is reserved from allocation.

Notwithstanding the above, presently existing legal uses for the duration of the permit existing on [effective date] are determined to be not contrary to the public interest, pursuant to Section 373.223(4), F.S.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.016, 373.026, 373.036, 373.1501, 373.1502, 373.219, 373.223, 373.4592, 373.4595, 373.470 FS. History–New _____.

APPENDIX 1 TO CHAPTER 40E-10
LEGAL DESCRIPTION OF PICAYUNE STRAND
AS DEFINED IN RULE 40E-10.021(1)

A tract of land in Townships 50, 51 and 52 South, Ranges 27 and 28 East, Collier County, Florida, more particularly described as follows:

Beginning at the Southeast Corner of Section 25, Township 51 South, Range 28 East, Collier County, Florida, run S 89°10'50" W, 2659.84 feet to the South Quarter Corner of said Section 25; thence S 89°09'41" W, 2659.37 feet to the Southwest Corner of

said Section 25; thence S 00°19'11" W, 2611.61 feet to the East Quarter Corner of Section 35 of said Township 51 South, Range 28 East;
thence S 88°56'33" W, 2652.73 feet to the Northeast Corner of the Southwest Quarter of said Section 35; thence S 00°18'15" W, 2614.86 feet to the South Quarter Corner of said Section 35; thence S 88°54'23" W, 2650.59 feet to the Southwest Corner of Section 35; thence S 88°50'39" W, 2639.94 feet to the South Quarter Corner of Section 34 of said Township 51 South, Range 28 East;
thence S 89°00'23" W, 2652.66 feet to the Southwest Corner of said Section 34;
thence S 88°44'21" W along the north line of the Northeast Quarter of Section 4, Township 52 South, Range 28 East, 1450.32 feet to the Northeast Corner of those lands described in Official Record Book 2624, Page 2509, Public Records of Collier County, Florida; thence S 00°27'37" E along the east line of said lands, 6308.01 feet; thence continuing along said east line, S 89°34'56" W, 16.37 feet;
thence continuing along said east line, S 00°25'04" E, 360.00 feet to the north right-of-way line of U.S. Highway 41; thence westerly along the north right-of-way line of U.S. Highway 41, S 84°52'54" W, 327.99 feet; thence N 05°07'06" W, 39.00 feet to a point on a non-tangent curve; thence westerly 900.69 feet along the arc of said curve, concave to the northeast, having a radius of 1835.08 feet, a central angle of 28°07'18" and a chord of 891.68 feet, bearing N 81°03'27" W;
thence S 23°00'12" W, 39.00 feet; thence N 66°59'48" W, 5570.19 feet to a point of curvature; thence northwesterly 800.00 feet along the arc of a curve, concave to the southwest, having a radius of 17224.80 feet, a central angle of 02°39'40" and a chord of 799.93 feet, bearing N 68°19'38" W to a point of tangency;
thence N 69°39'28" W, 6844.52 feet; thence N 20°20'32" E, 39.00 feet to a point on a non-tangent curve; thence northwesterly 671.08 feet along the arc of said curve, concave to the northeast, having a radius of 1835.08 feet, a central angle of 20°57'10" and a chord of 667.35 feet, bearing N 59°10'53" W; thence
S 41°17'43" W, 39.00 feet; thence N 48°42'17" W, 6815.31 feet to a point of curvature; thence northwesterly 442.16 feet along the arc of a curve, concave to the southwest, having a radius of 725.20 feet, a central angle of 34°56'02" and a chord of 435.35 feet, bearing N 66°10'19" W to a point of tangency; thence
N 83°38'20" W, 300.77 feet to the intersection of the north right-of-way line of U.S. Highway 41 with the west line of Section 36, Township 51 South, Range 27 East;
thence N 00°03'59" E along the west line of said Section 36, 1586.32 feet to the Northwest Corner of Section 36; thence N 01°15'40" W, 2658.40 feet, to the West Quarter Corner of Section 25 of said Township 51 South, Range 27 East;
thence N 01°17'06" W, 2656.42 feet to the Northwest Corner of said Section 25;
thence N 01°16'05" W, 2655.83 feet to the West Quarter Corner of Section 24 of said Township 51 South, Range 27 East; thence N 01°16'15" W, 2656.76 feet to the Northwest Corner of said Section 24; thence N 00°19'01" E, 2764.38 feet to the West Quarter Corner of Section 13 of said Township 51 South, Range 27 East; thence N 00°19'04" E, 2764.32 feet to the Northwest Corner of said Section 13; thence N 01°15'53" E, 2764.69 feet to the West Quarter Corner of Section 12 of said Township 51 South, Range 27 East; thence N 01°16'08" E, 2764.72 feet to the Northwest Corner of said Section 12; thence N 00°37'07" E, 2763.78 feet to the West Quarter Corner of Section 1 of said Township 51 South, Range 27 East; thence N 00°35'09" E, 2732.08 feet to the Northwest Corner of said Section 1; thence N 01°09'58" E, 2697.35 feet to the West Quarter Corner of Section 36 of Township 50 South, Range 27 East; thence N 01°14'25" E, 2554.73 feet to the Northwest Corner of said Section 36; thence N 00°49'11" E, 2618.76 feet to the West Quarter Corner of Section 25 of said Township 50 South, Range 27 East;
thence N 01°30'13" E, 2623.02 feet to the Northwest Corner of said Section 25;
thence N 01°14'51" E, 2643.78 feet to the West Quarter Corner of Section 24 of said Township 50 South, Range 27 East; thence N 00°55'45" E, 2647.27 feet to the Northwest Corner of said Section 24; thence N 89°04'28" W, 2655.08 feet to the South Quarter Corner of Section 14 of said Township 50 South, Range 27 East; thence N 89°06'09" W, 2673.56 feet to the Southwest Corner of said Section 14; thence N 01°20'52" E, 2642.45 feet to the West Quarter Corner of said Section 14; thence N 01°02'27" E, 2638.34 feet to the Northwest Corner of said Section 14; thence S 88°57'18" E, 2650.45 feet to the North Quarter Corner of said Section 14; thence S 89°16'05" E, 2679.46 feet to the Northeast Corner of said Section 14; thence N 00°32'07" E, 2629.53 feet to the West Quarter Corner of Section 12 of said Township 50 South, Range 27 East; thence N 00°05'55" E, 2655.64 feet to the Northwest Corner of said Section 12; thence N 00°35'20" E, 2638.33 feet to the West Quarter Corner of Section 1 of said Township 50 South, Range 27 East; thence N 09°11'51" W along the west line of the Northwest Quarter of said Section 1 a distance of 2352.20 feet to the intersection with the south line of the south drainage right-of-way of Interstate 75; thence easterly along said line, N 89°40'16" E, 2640.00 feet; thence S 88°14'35" E, 2676.02 feet;
thence S 89°13'04" E, 2656.26 feet; thence N 89°51'50" E, 2650.84 feet;
thence N 89°28'53" E, 2647.15 feet; thence S 89°53'38" E, 2654.08 feet;
thence S 89°59’57" E, 2650.10 feet; thence N 89°51'03" E, 2650.97 feet;
thence S 89°32'18" E, 2648.17 feet; thence N 89°47'26" E, 2686.92 feet;
thence N 00°23'28" W, 124.56 feet; thence S 89°54'09" E, 2649.59 feet;

thence S 89°56'18" E, 2651.63 feet; thence N 89°41'16" E, 2652.50 feet;
thence S 89°49'15" E, 2651.54 feet to the intersection of the south line of said south drainage right-of-way with the east line of Section 1, Township 50 South, Range 28 East; thence S 00°18'22" E along the east line of the Northeast Quarter of said Section 1 a distance of 2460.78 feet to the East Quarter Corner of said Section 1; thence S 00°18'26" E, 2663.16 feet to the Southeast Corner of said Section 1; thence S 00°19'17" E, 2661.71 feet to the East Quarter Corner of Section 12 of said Township 50 South, Range 28 East; thence S 00°18'47" E, 2661.88 feet to the Southeast Corner of said Section 12; thence S 00°18'10" E, 2662.06 feet to the East Quarter Corner of Section 13 of said Township 50 South, Range 28 East; thence S 00°18'16" E, 2662.13 feet to the Southeast Corner of said Section 13; thence S 00°18'16" E, 2662.14 feet to the East Quarter Corner of Section 24 of said Township 50 South, Range 28 East; thence S 00°17'28" E, 2661.81 feet to the Southeast Corner of said Section 24; thence S 00°17'38" E, 2674.16 feet to the East Quarter Corner of Section 25 of said Township 50 South, Range 28 East; thence S 00°10'00" E, 2674.56 feet to the Southeast Corner of said Section 25; thence S 00°13'47" E, 2674.47 feet to the East Quarter Corner of Section 36 of said Township 50 South, Range 28 East; thence S 00°13'47" E, 2674.49 feet to the Southeast Corner of said Section 36; thence S 00°51'18" E, 2682.32 feet to the East Quarter Corner of Section 1 of Township 51 South, Range 28 East; thence S 00°51'18" E, 2682.32 feet to the Southeast Corner of said Section 1; thence S 00°28'26" W, 2596.09 feet to the East Quarter Corner of Section 12 of said Township 51 South, Range 28 East; thence S 00°41'47" W, 2598.68 feet to the Southeast Corner of said Section 12; thence southerly along the east line of Section 13, Township 51 South, Range 28 East, S 00°35'55" W, 5191.01 feet to the Southeast Corner of said Section 13; thence S 00°36'41" W, 2596.95 feet to the East Quarter Corner of Section 24 of said Township 51 South, Range 28 East; thence S 00°34'08" W, 2597.43 feet to the Southeast Corner of said Section 24; thence S 00°33'57" W, 2596.90 feet to the East Quarter Corner of Section 25 of said Township 51 South, Range 28 East; thence S 00°34'27" W, 2597.76 feet to the Southeast Corner of said Section 25 and the Point of Beginning.

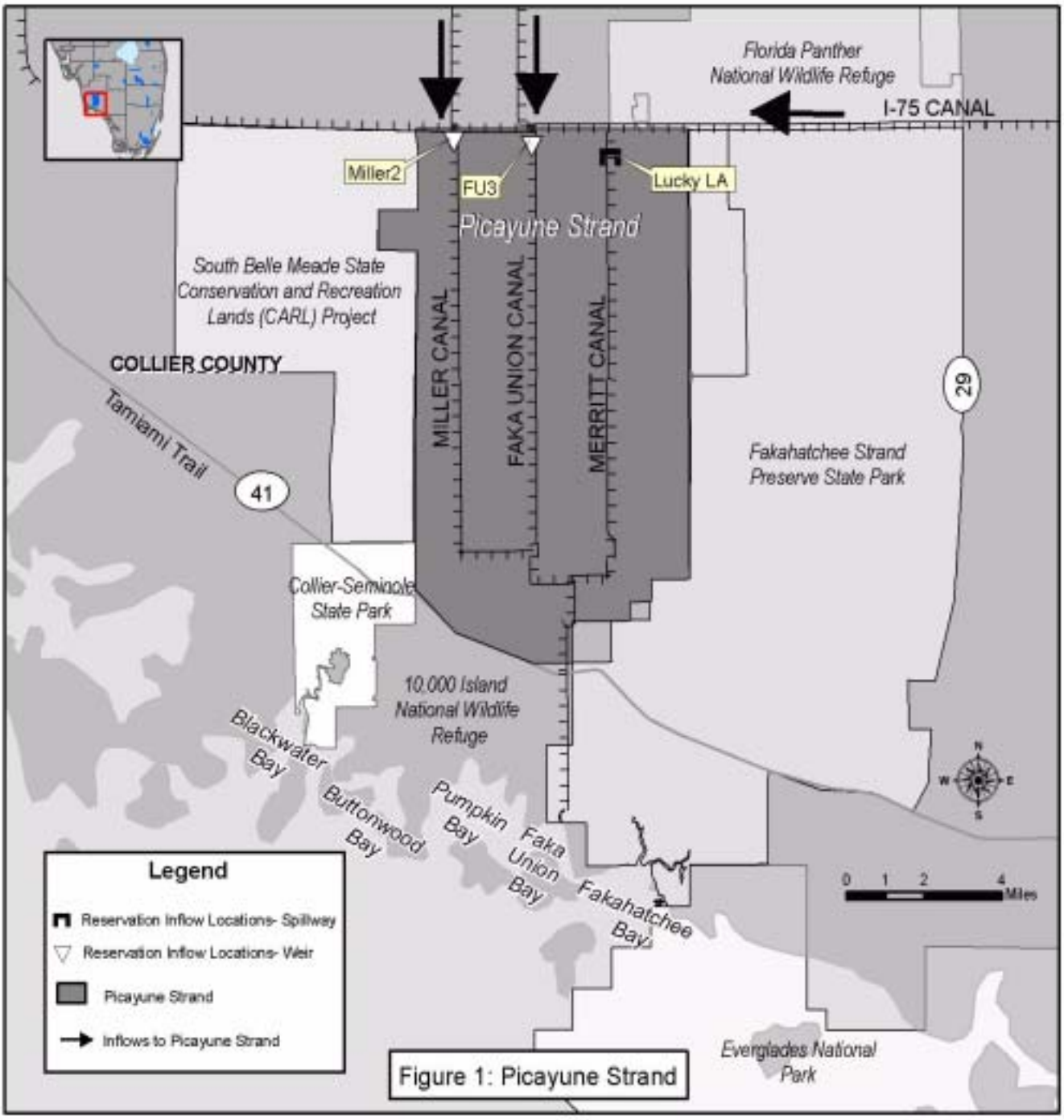


Figure 1: Picayune Strand

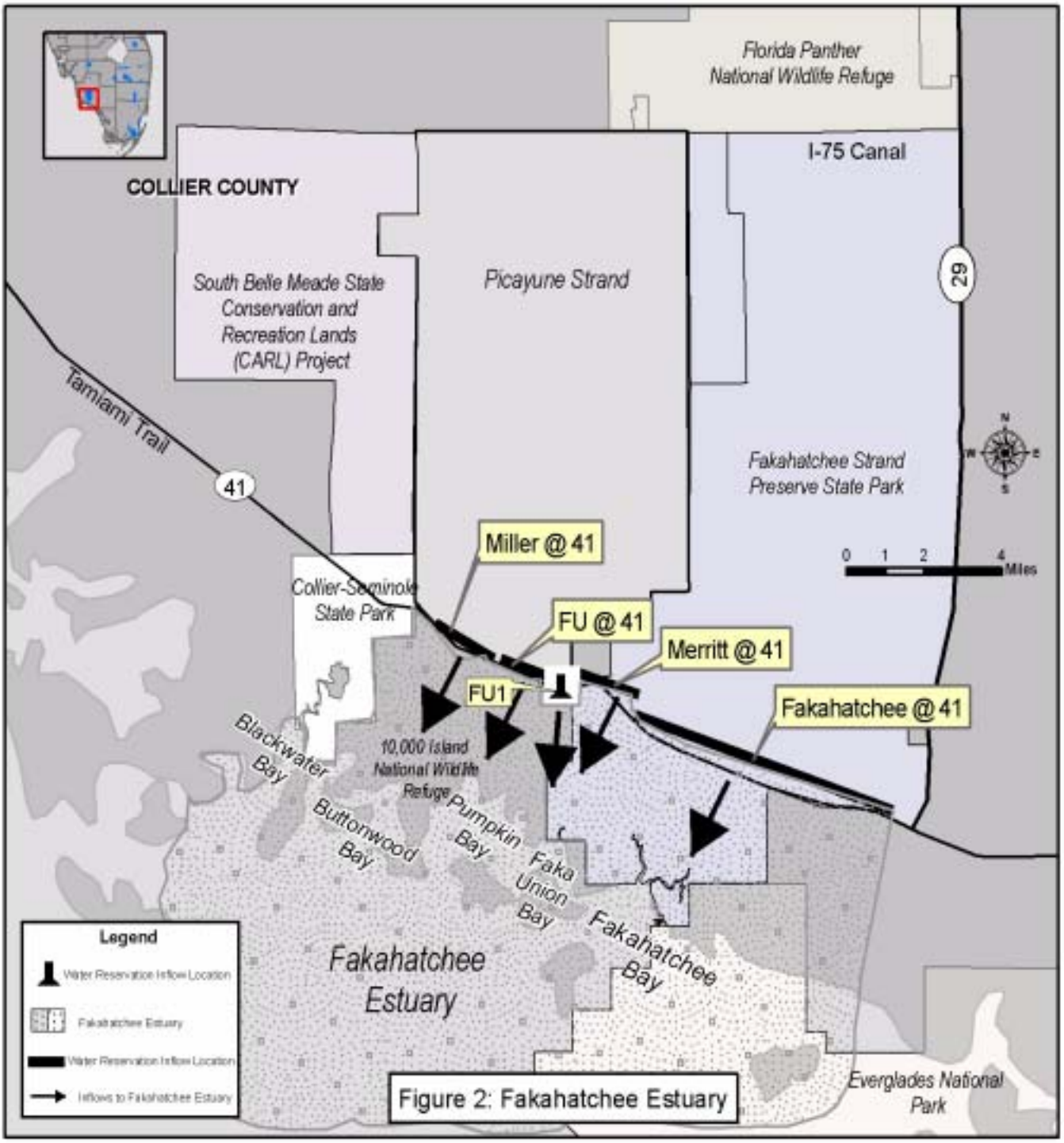


Figure 2: Fakahatchee Estuary

Figure 3.A. Simulated Surface Water Inflow From Miller Canal Near I-75
Volume Probability Curve - 1988 Through 2000

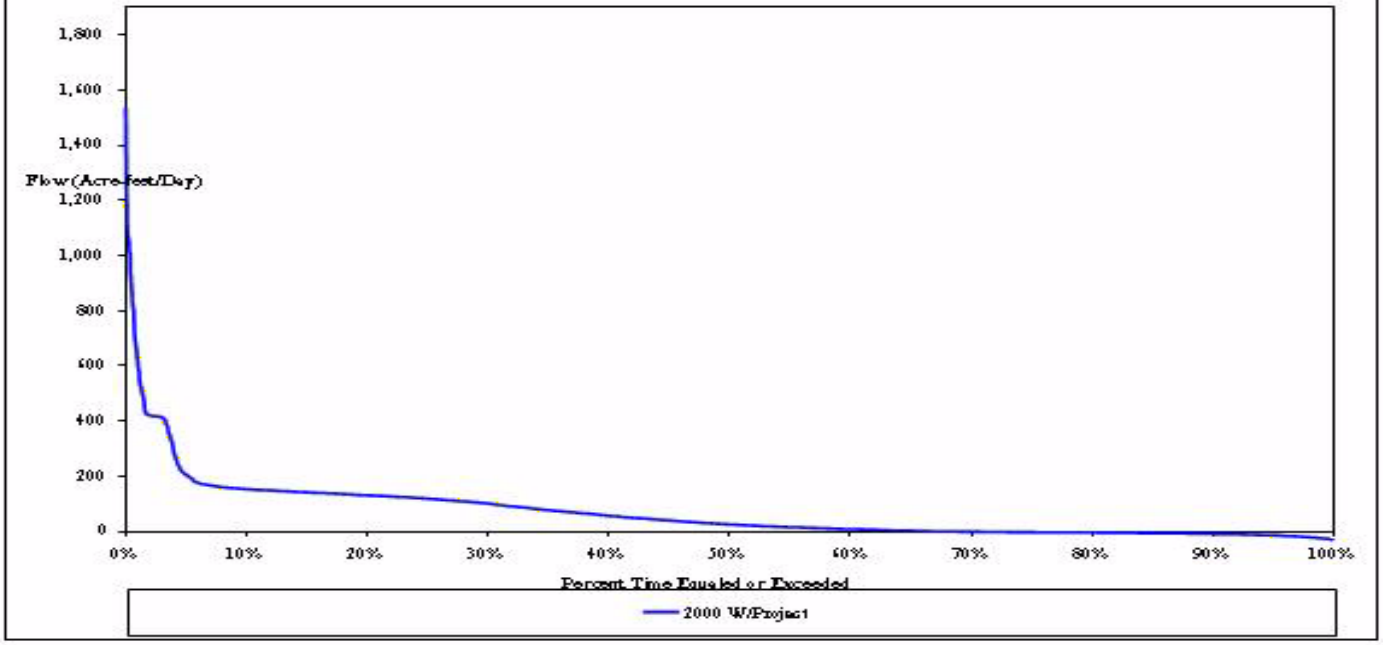
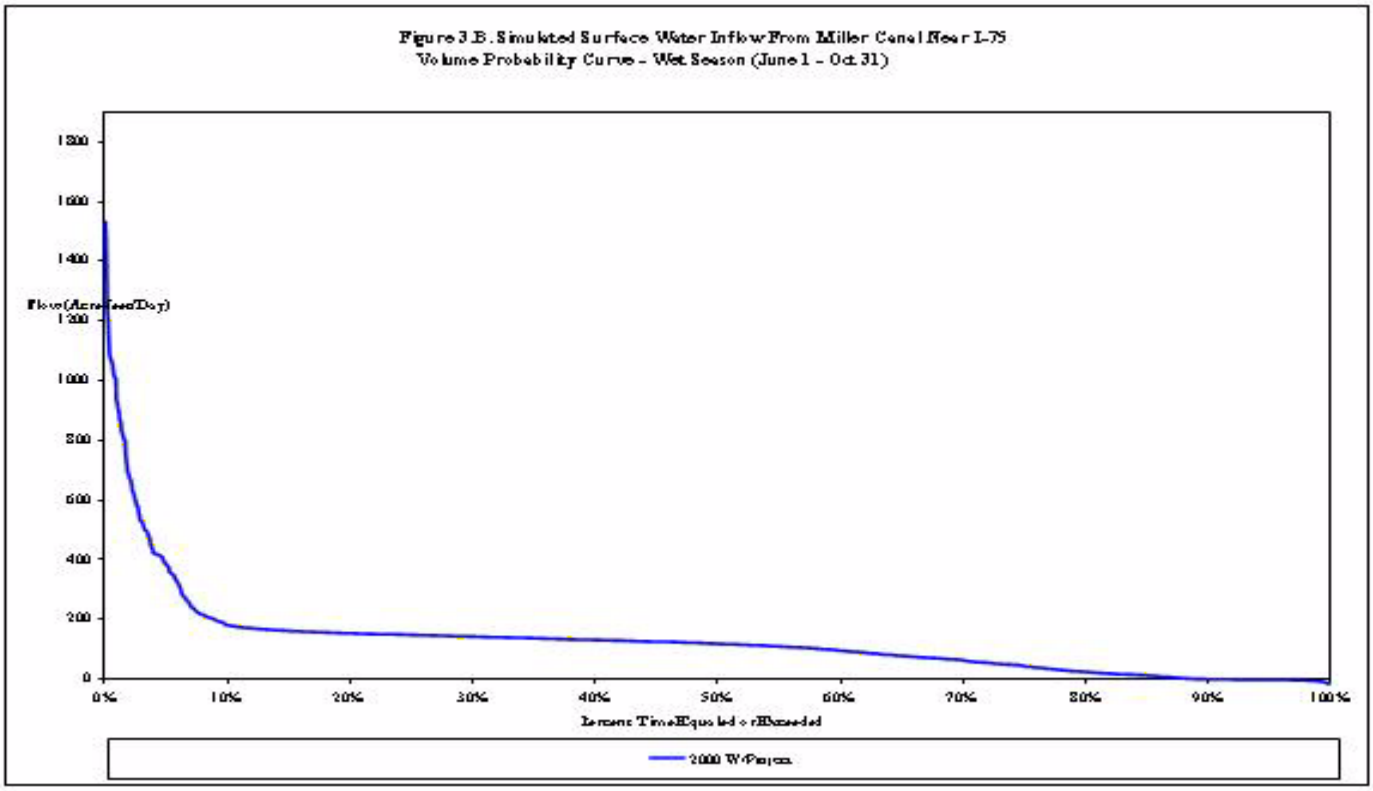


Figure 3.B. Simulated Surface Water Inflow From Miller Canal Near I-75
Volume Probability Curve - Wet Season (June 1 - Oct 31)



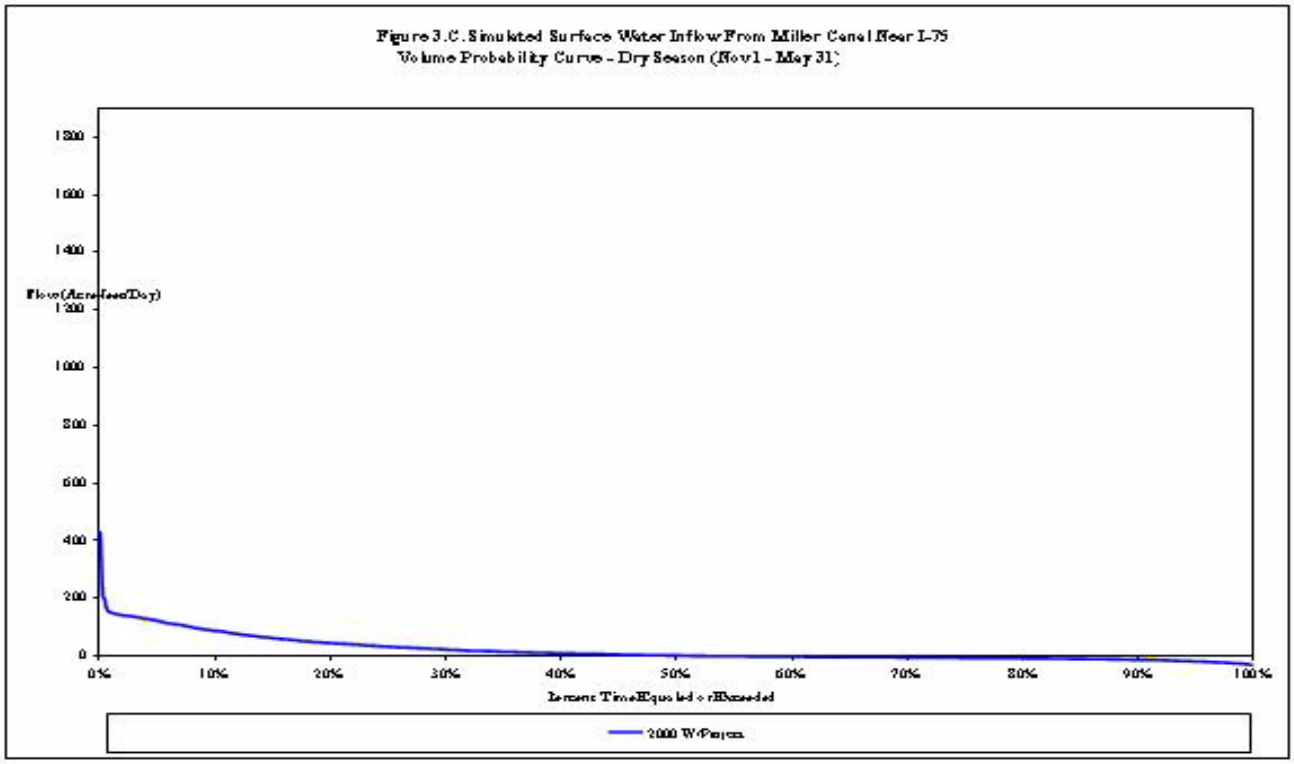


Figure 3.C. Simulated Surface Water Inflow From Miller Canal Near I-75
Volume Probability Curve - Dry Season (Nov 1 - May 31)
1800
1600
1400
1200
1000
800
600
400
200
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
2000 W/Project

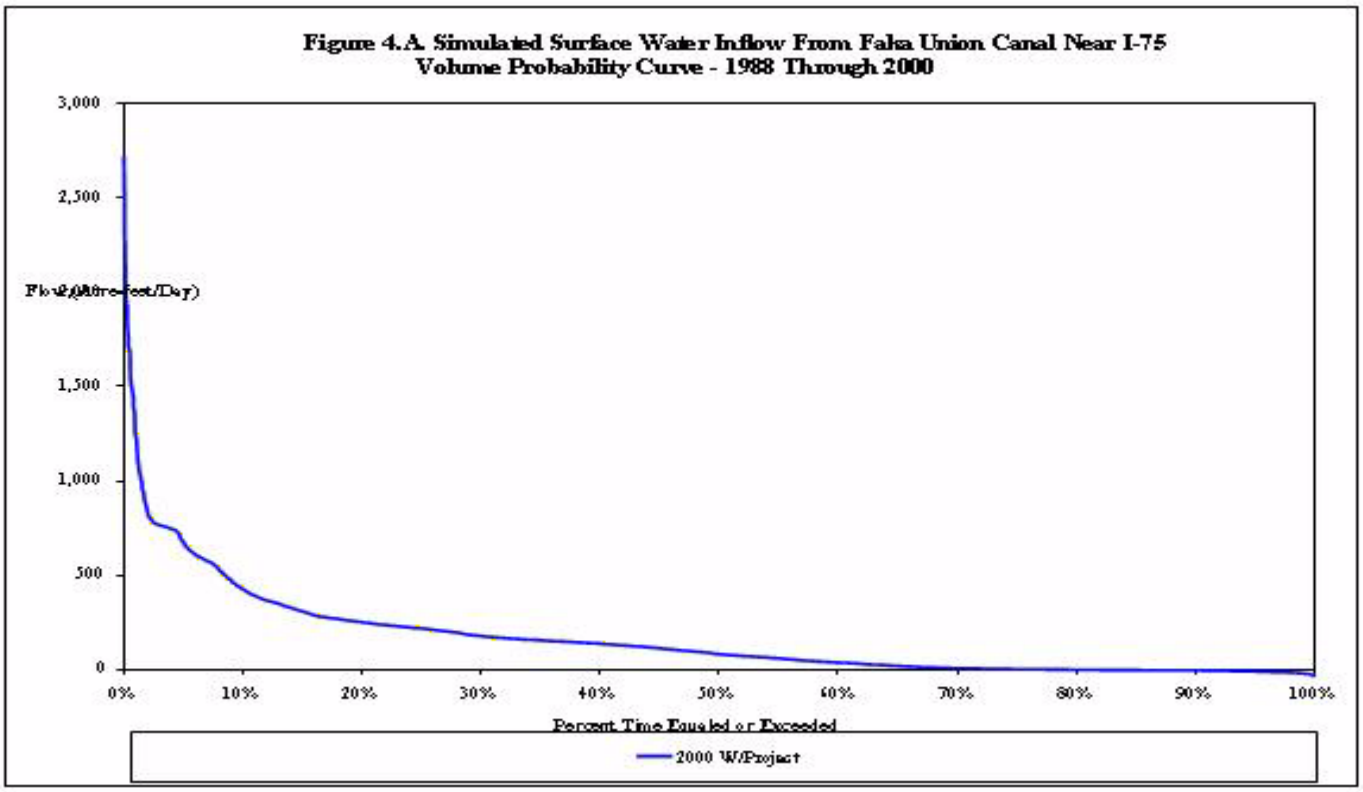


Figure 4.A. Simulated Surface Water Inflow From Faka Union Canal Near I-75
Volume Probability Curve - 1988 Through 2000
3,000
2,500
1,500
1,000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percent Time Equaled or Exceeded
2000 W/Project

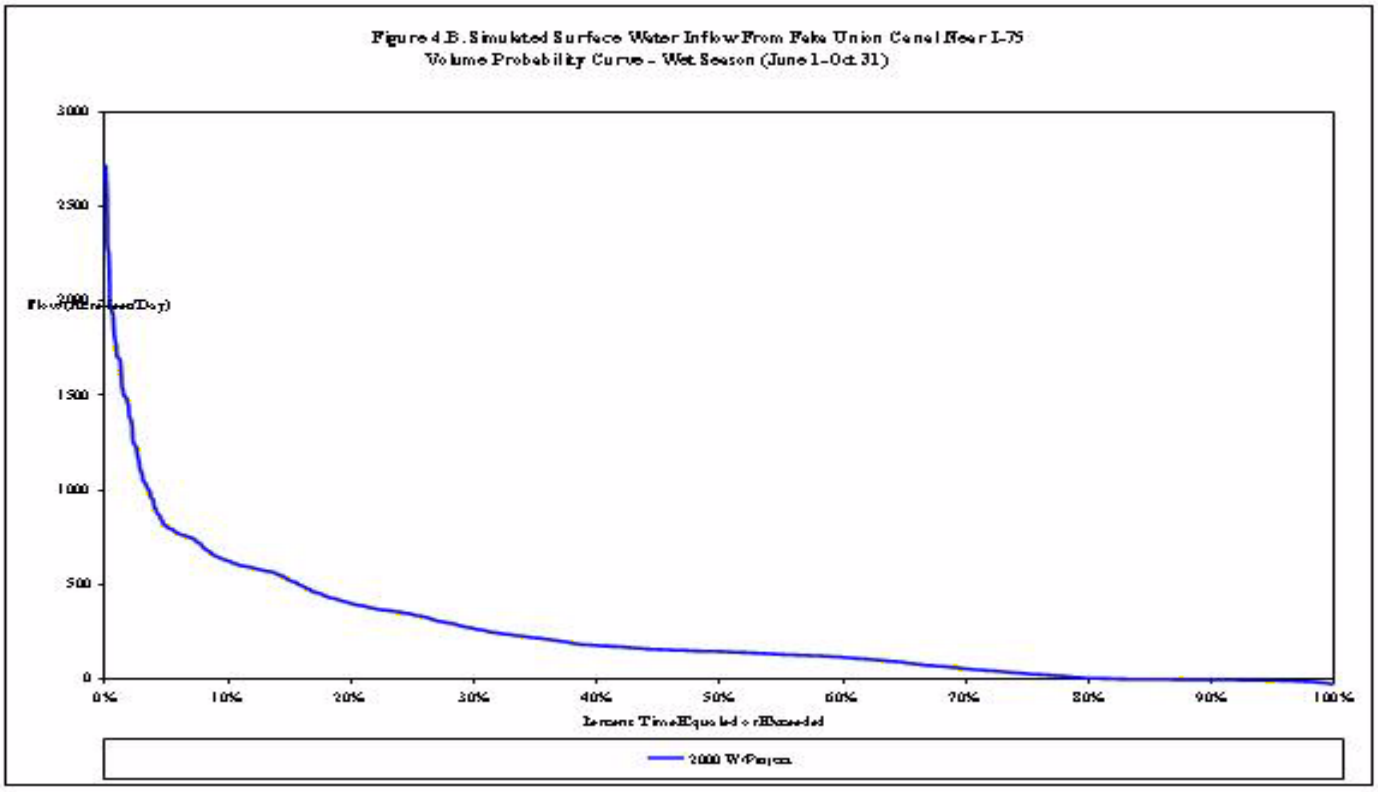


Figure 4.B. Simulated Surface Water Inflow From Fake Union Canal Near I-75
Volume Probability Curve - Wet Season (June 1-Oct 31)
3000
2500
2000
1500
1000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
2000 W/Project

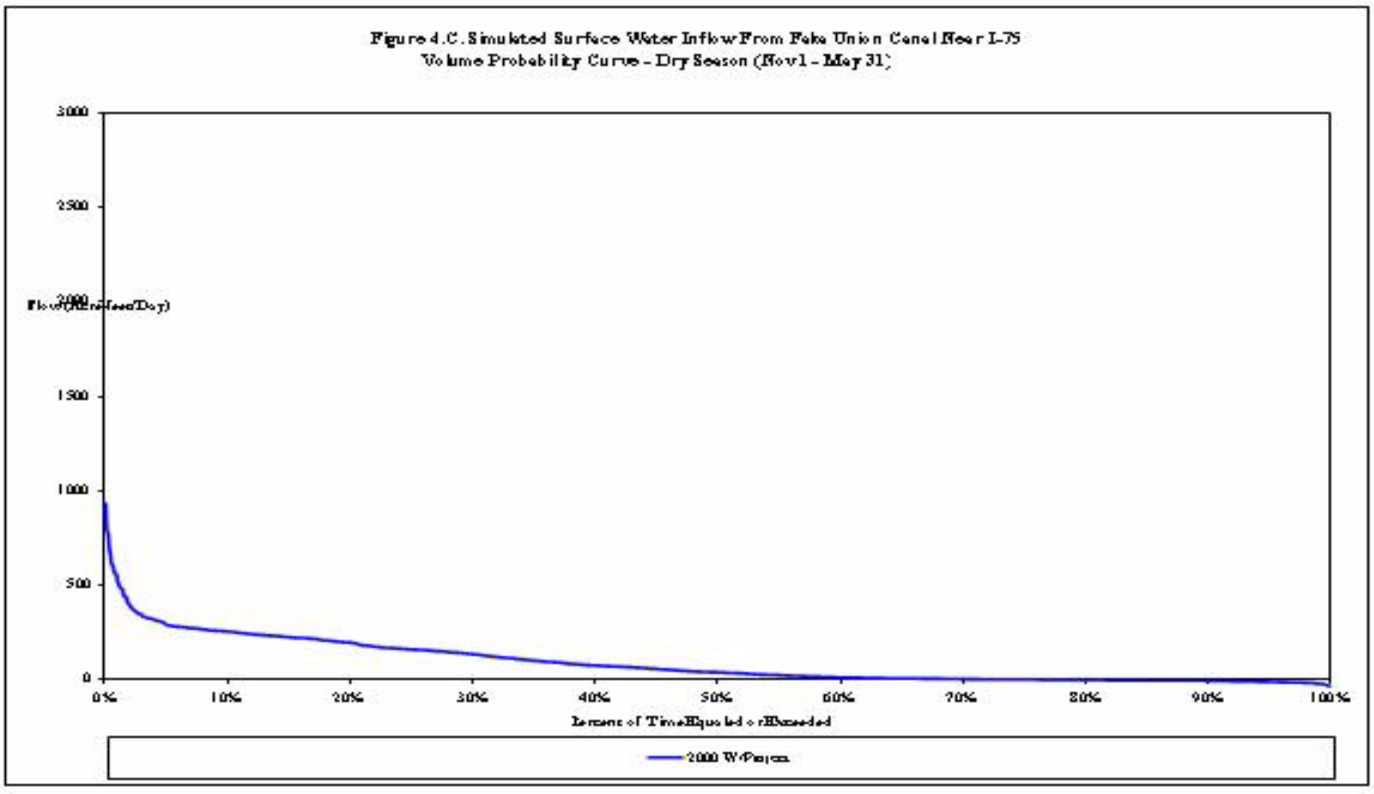


Figure 4.C. Simulated Surface Water Inflow From Fake Union Canal Near I-75
Volume Probability Curve - Dry Season (Nov 1 - May 31)
3000
2500
2000
1500
1000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
2000 W/Project

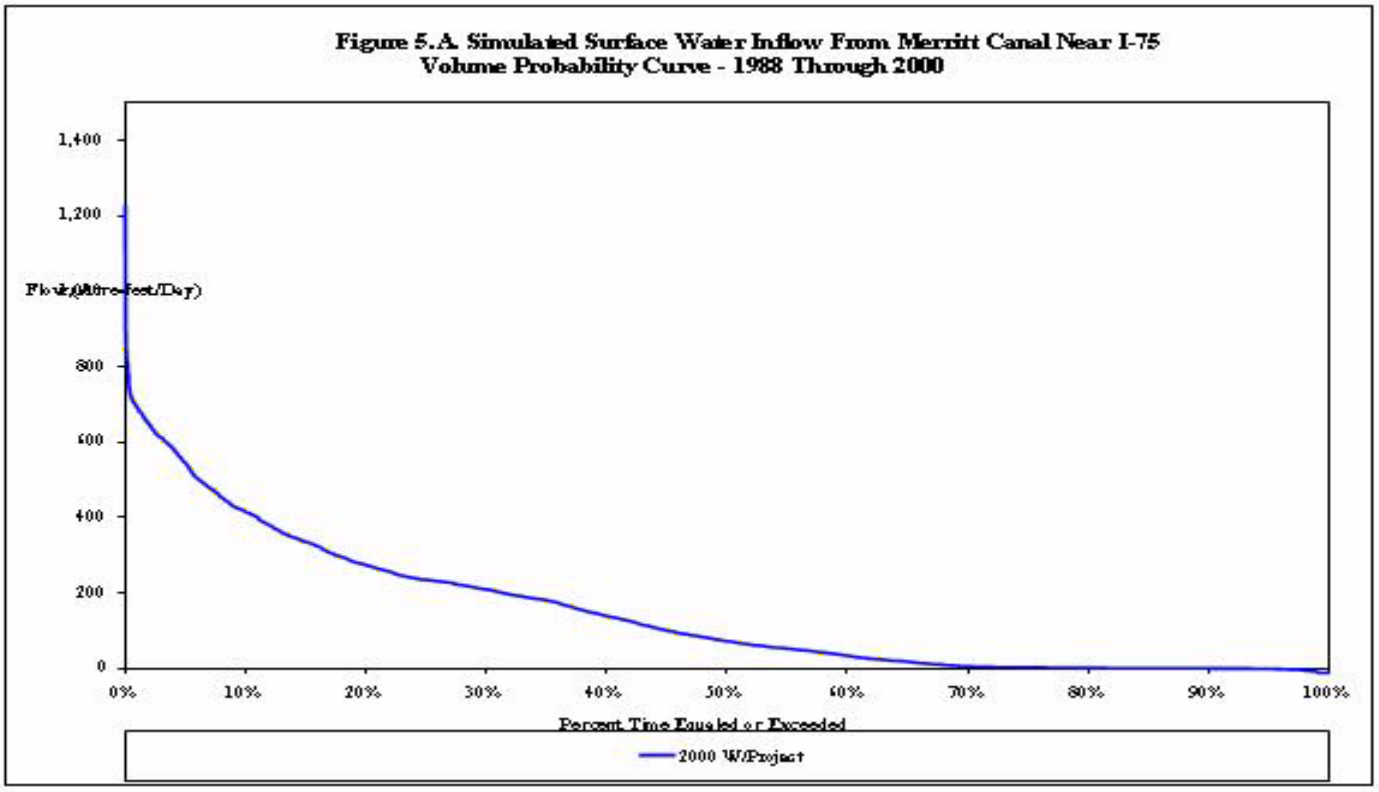


Figure 5.A. Simulated Surface Water Inflow From Merritt Canal Near I-75
Volume Probability Curve - 1988 Through 2000
1,400
1,200
800
600
400
200
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percent Time Equaled or Exceeded
2000 W/Project

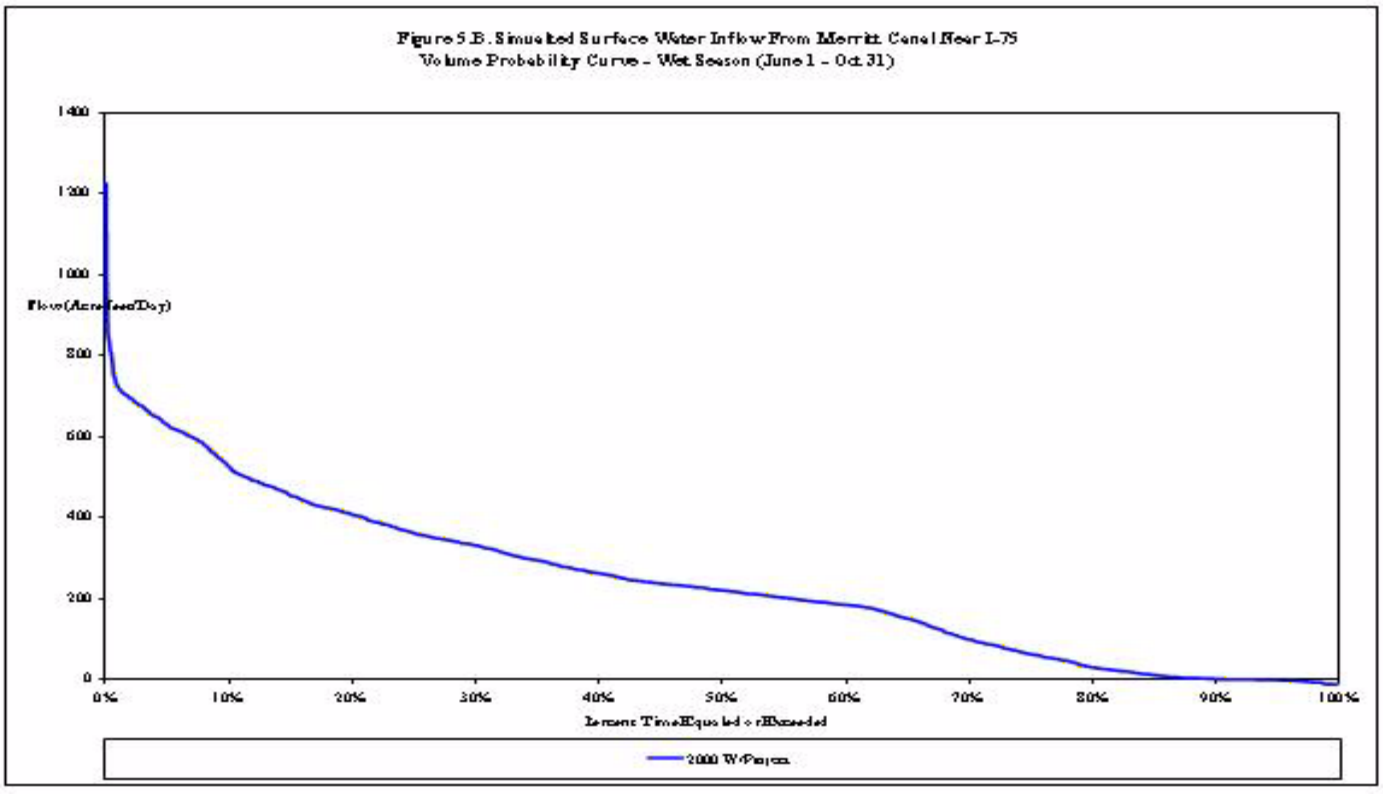


Figure 5.B. Simulated Surface Water Inflow From Merritt Canal Near I-75
Volume Probability Curve - Wet Season (June 1 - Oct 31)
1400
1200
1000
800
600
400
200
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
2000 W/Project

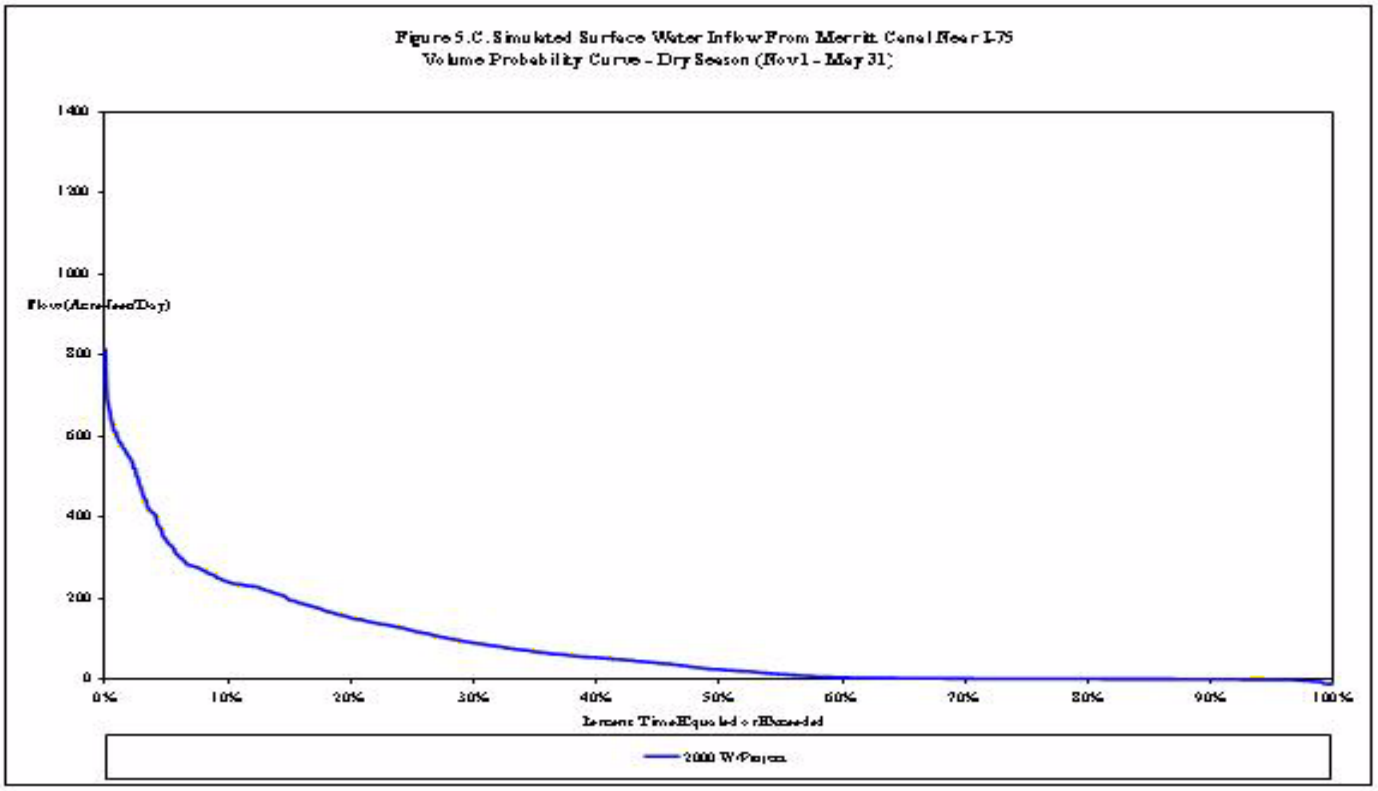


Figure 6.A. Simulated Surface Water Deliveries to Faka Union Bay From Faka Union FU#1 Near US 41 Volume Probability Curve – 1988 Through 2000

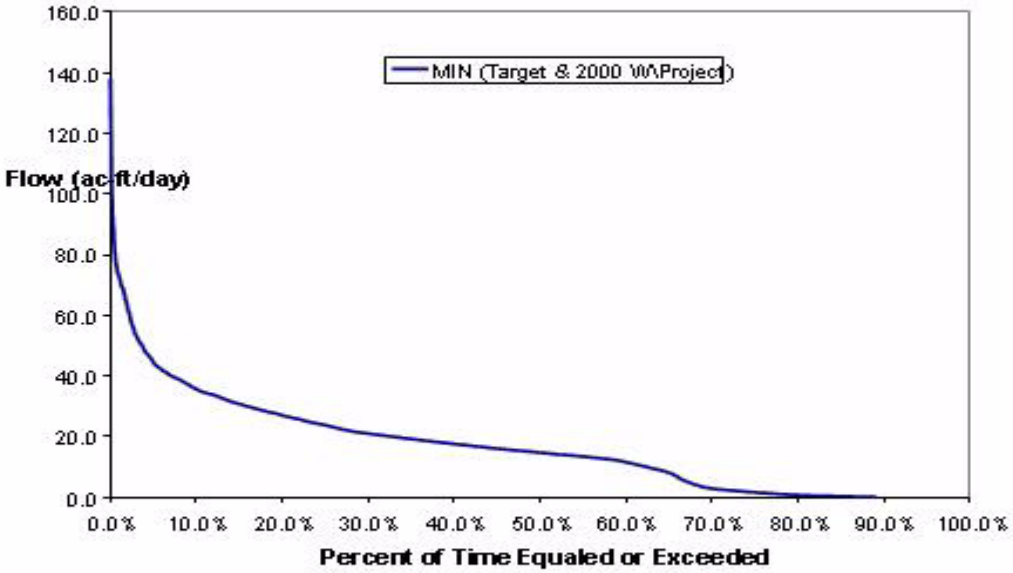


Figure 6.B. Simulated Surface Water Deliveries to Faka Union Bay from Faka Union FU#1 Near US 41 Wet Season Volume Probability Curve – (June 1 - Oct 31)

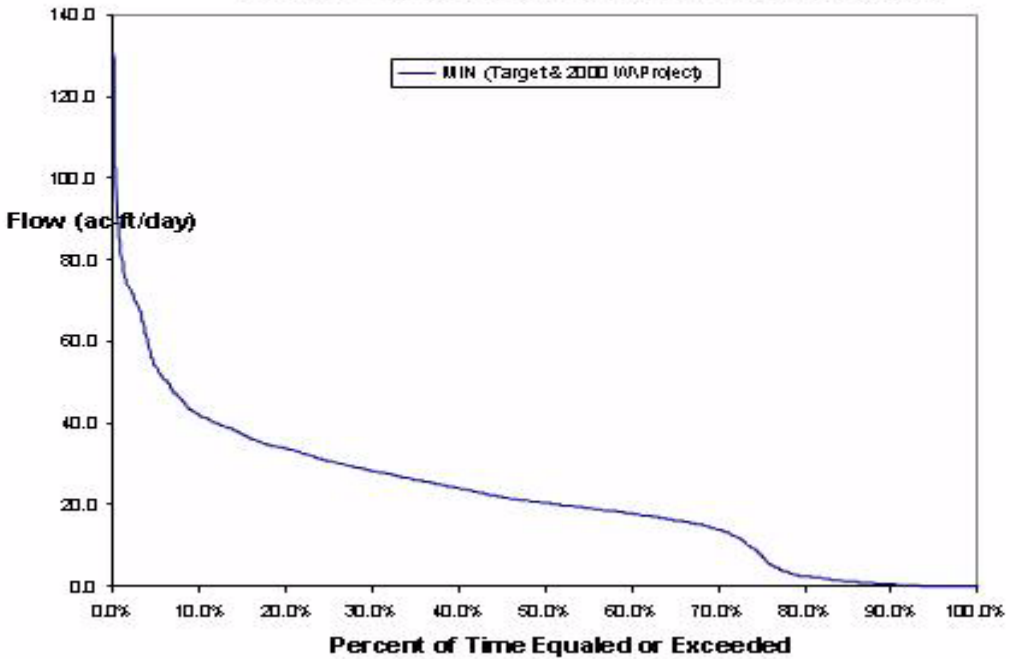
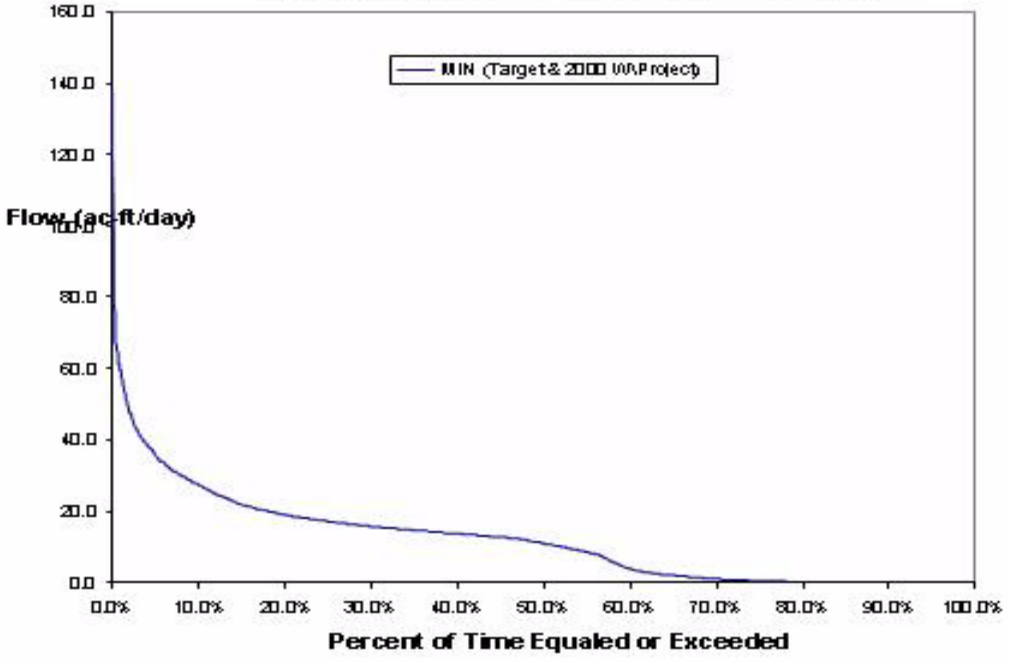


Figure 6.C. Simulated Surface Water Deliveries to Faka Union Bay from Faka Union FU#1 Near US 41 Dry Sesaon Volume Probability Curve (Nov 1 - May 31)



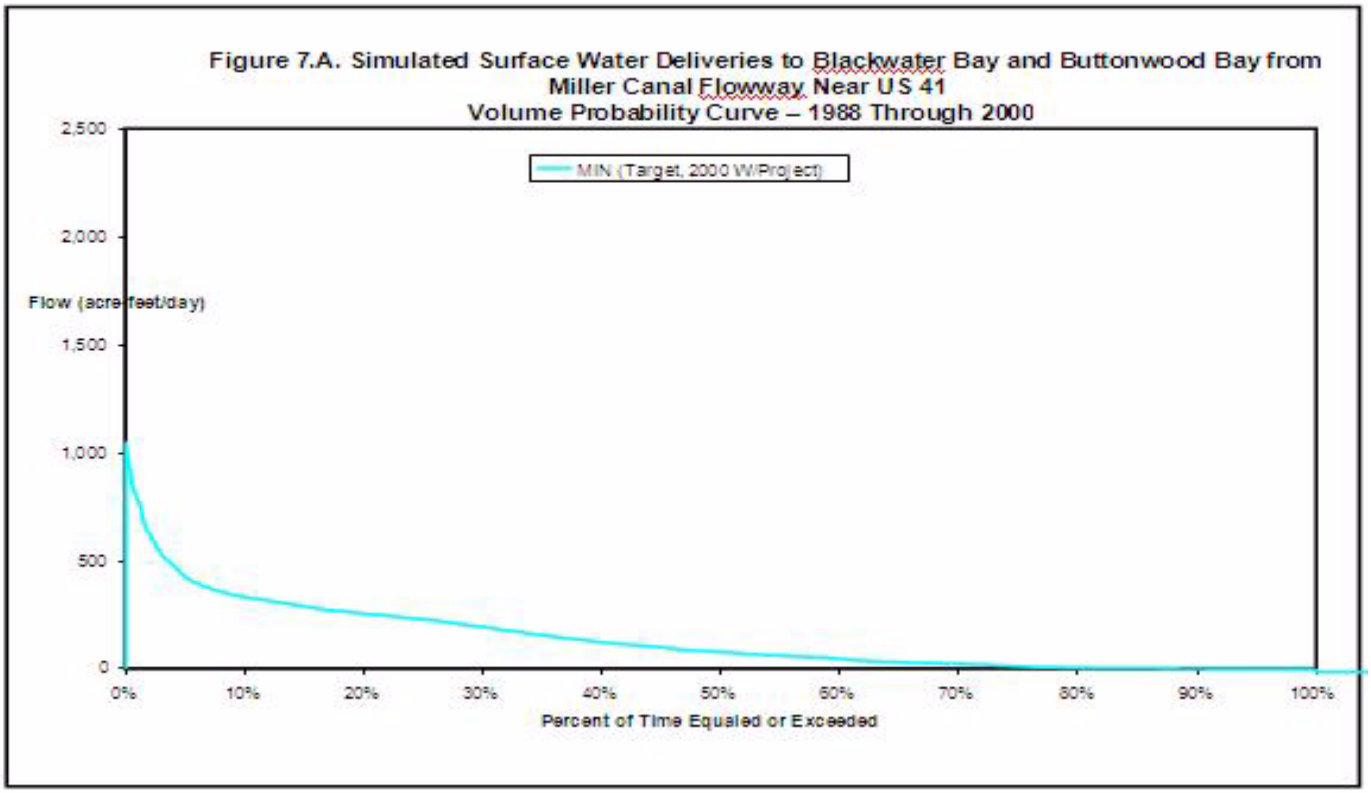


Figure 7.A. Simulated Surface Water Deliveries to Blackwater Bay and Buttonwood Bay from Miller Canal Flowway Near US 41
Volume Probability Curve – 1988 Through 2000
MIN (Target, 2000 W/Project)
Flow (acre-feet/day)
2,500
2,000
1,500
1,000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percent of Time Equaled or Exceeded

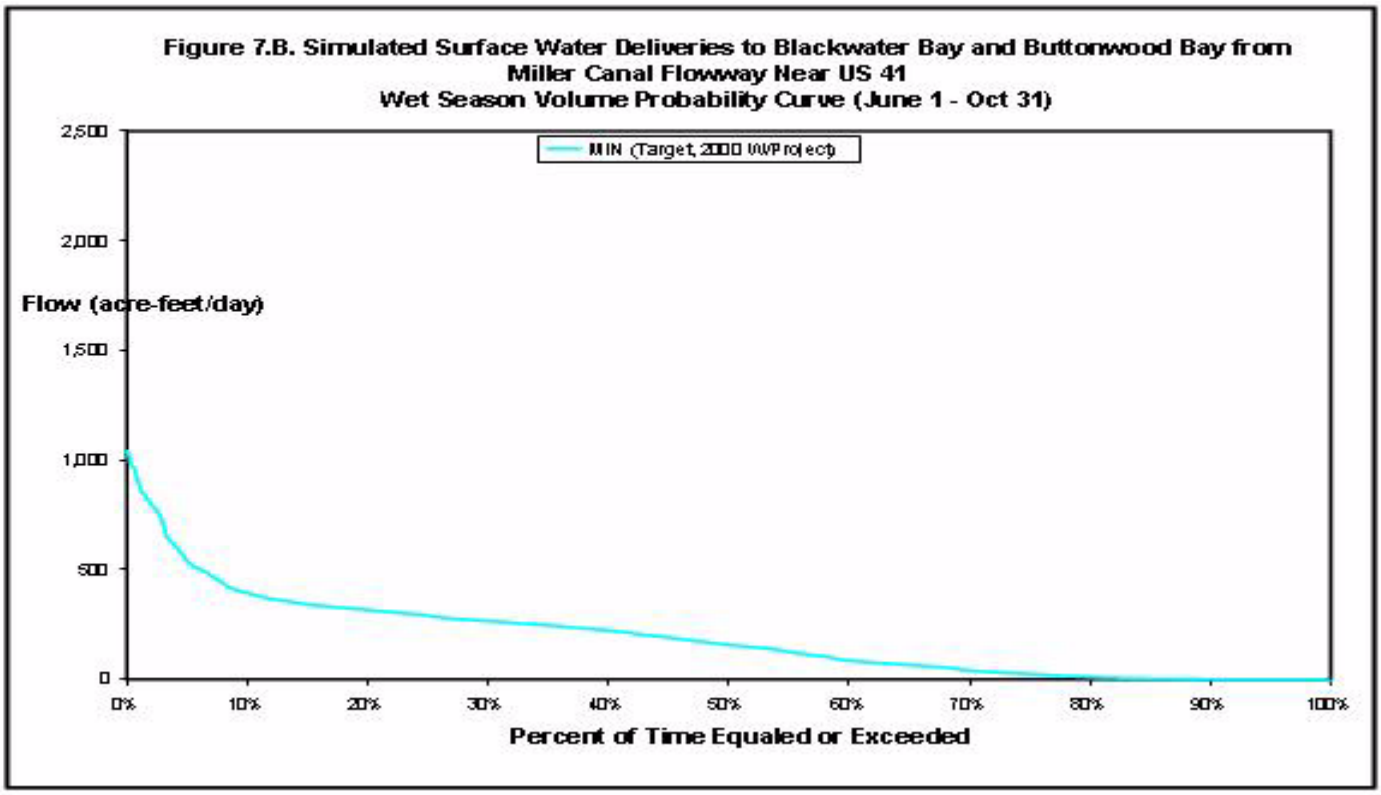


Figure 7.B. Simulated Surface Water Deliveries to Blackwater Bay and Buttonwood Bay from Miller Canal Flowway Near US 41
Wet Season Volume Probability Curve (June 1 - Oct 31)
MIN (Target, 2000 W/Project)
Flow (acre-feet/day)
2,500
2,000
1,500
1,000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percent of Time Equaled or Exceeded

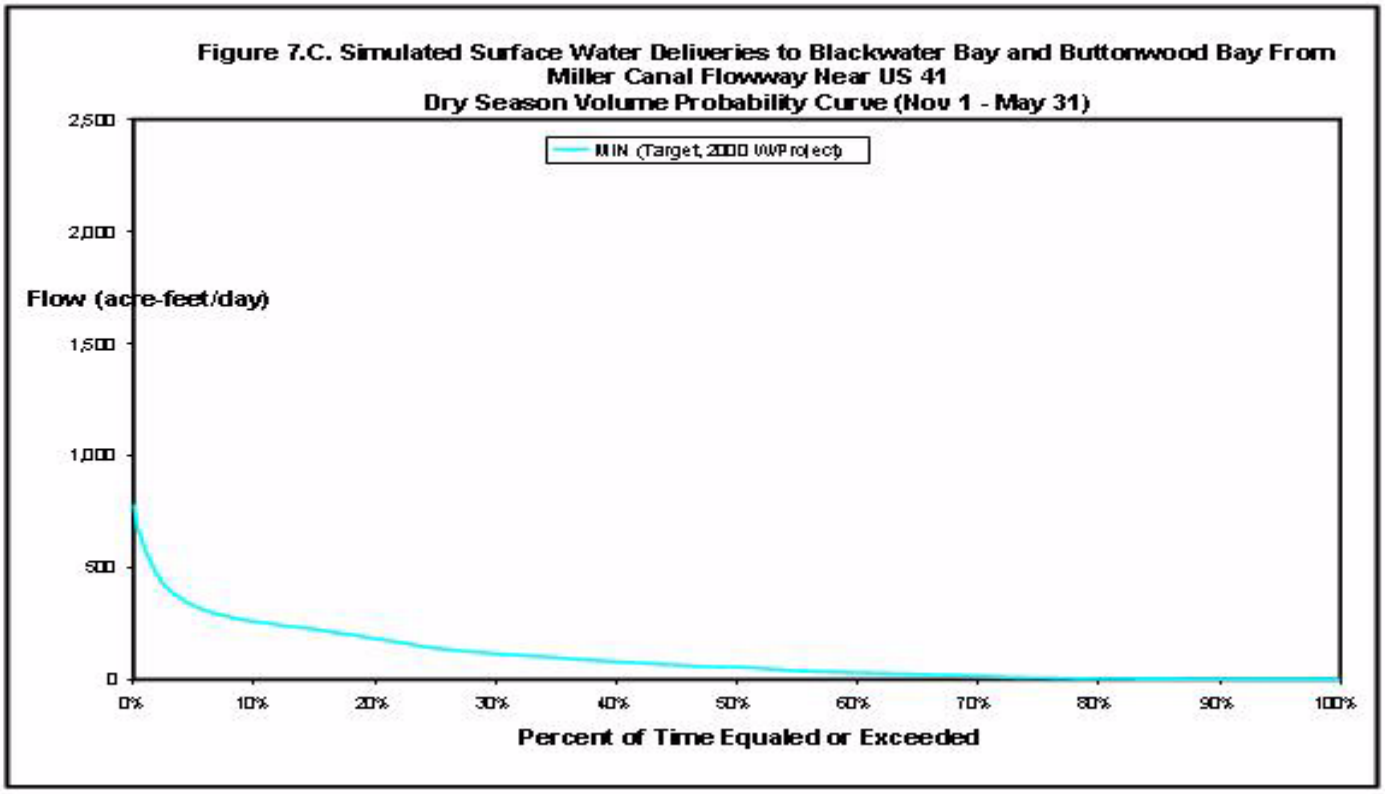


Figure 7.C. Simulated Surface Water Deliveries to Blackwater Bay and Buttonwood Bay From
Miller Canal Flowway Near US 41
Dry Season Volume Probability Curve (Nov 1 - May 31)
MIN (Target 2000 WPProject)
Flow (acre-feet/day)
2,500
2,000
1,500
1,000
500
0
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Percent of Time Equaled or Exceeded

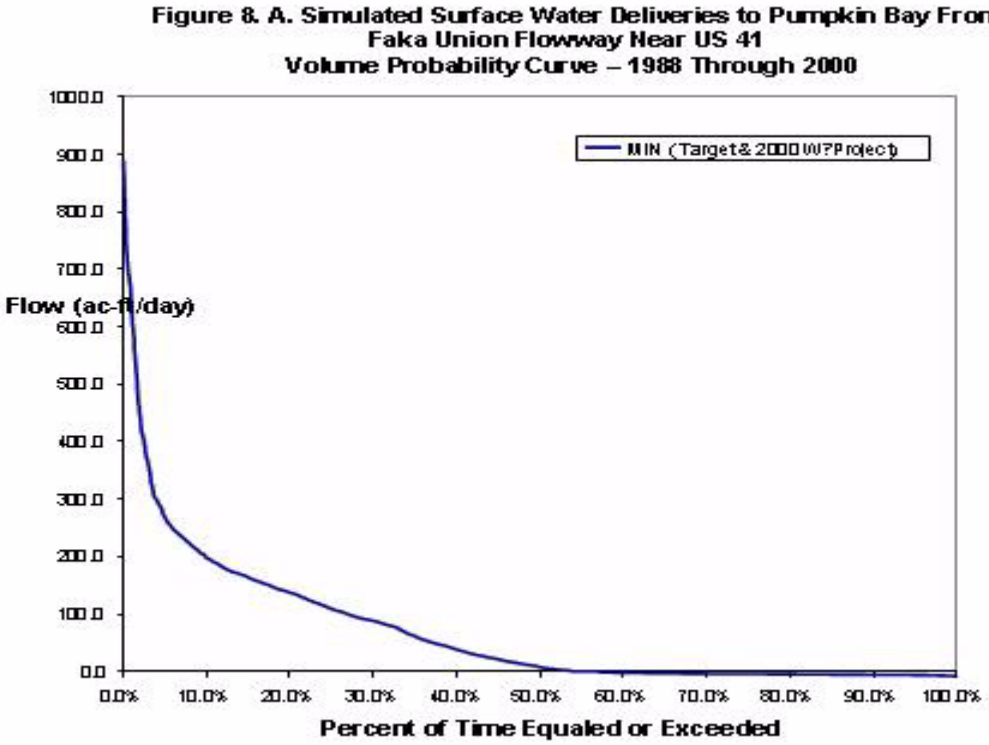


Figure 8. A. Simulated Surface Water Deliveries to Pumpkin Bay From
Faka Union Flowway Near US 41
Volume Probability Curve – 1988 Through 2000
MIN (Target & 2000 WPProject)
Flow (ac-ft/day)
1000.0
900.0
800.0
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
0.0%
10.0%
20.0%
30.0%
40.0%
50.0%
60.0%
70.0%
80.0%
90.0%
100.0%
Percent of Time Equaled or Exceeded

Figure 8.B. Simulated Surface Water Deliveries to Pumpkin Bay from Faka Union Flowway Near US 41 Wet Season Volume Probability Curve (June 1 - Oct 31)

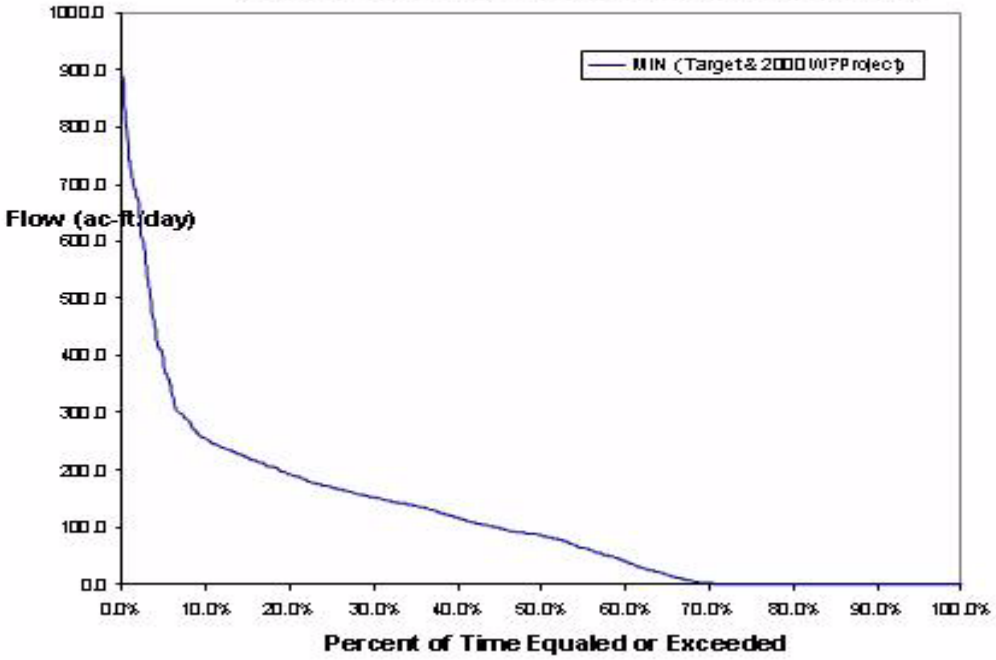


Figure 8.C. Simulated Surface Water Deliveries to Pumpkin Bay from Faka Union Flowway Near US 41 Dry Season Volume Probability Curve (Nov1 - May 31)

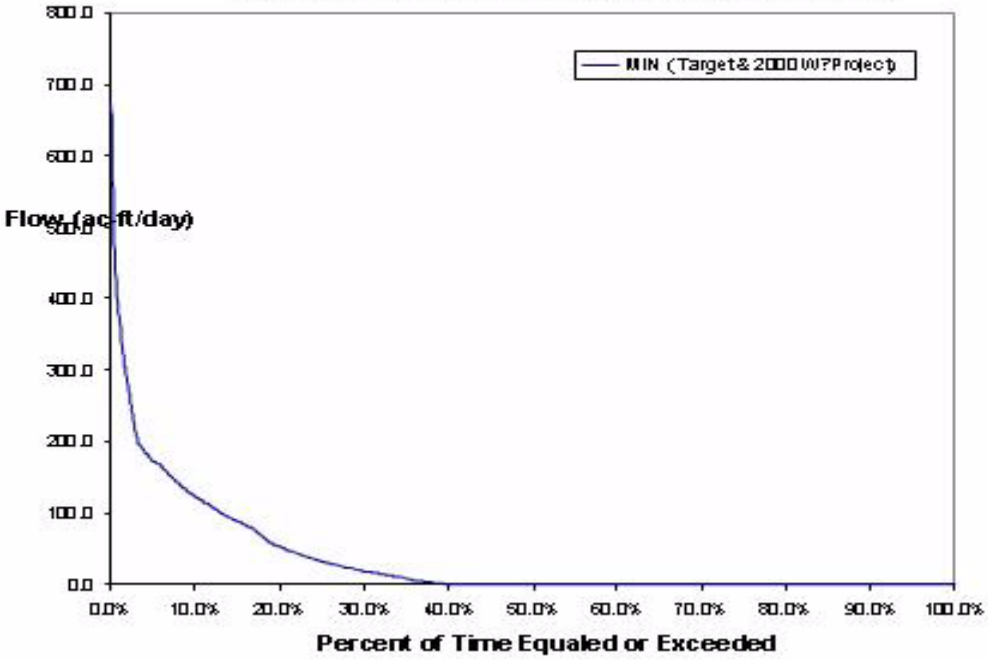


Figure 9.A. Simulated Surface Water Deliveries to Faka Union Bay From Merritt Canal Flowway Near US41 Volume Probability Curve – 1988 Through 2000

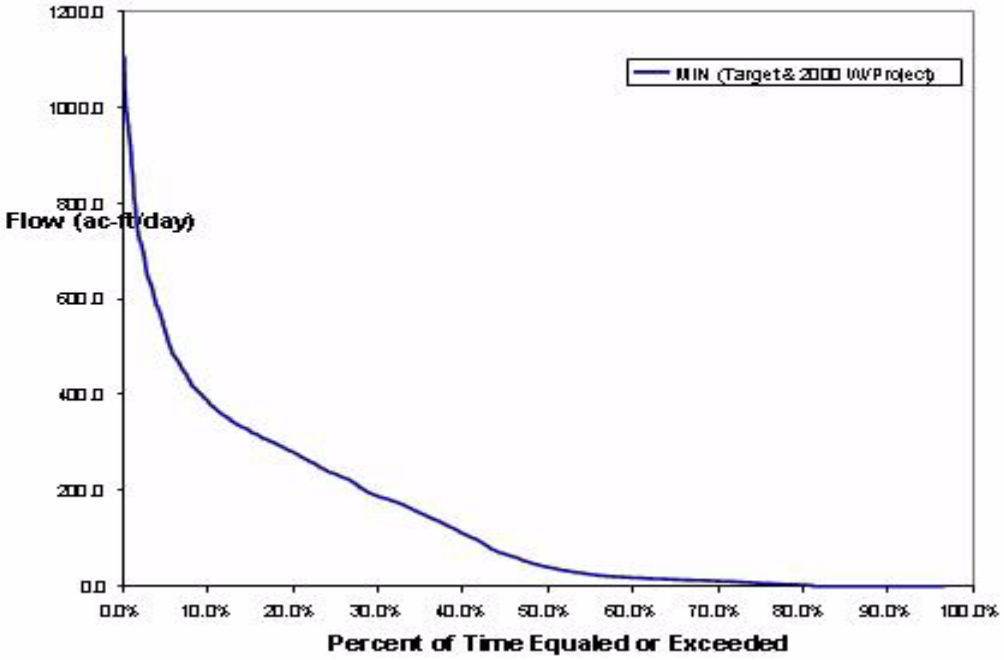


Figure 9.B. Simulated Surface Water Deliveries to Faka Union Bay from Merritt Canal Flowway Near US41 Wet Sesaon Volume Probability Curve (June 1- Oct 31)

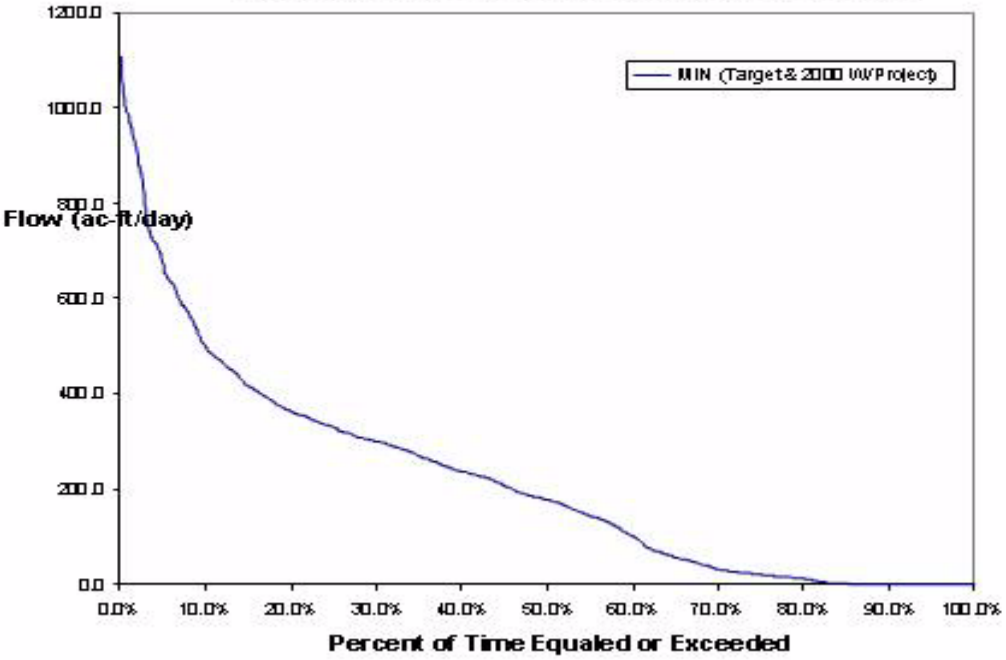


Figure 9.C. Simulated Surface Water Deliveries to Faka Union Bay from Merritt Canal Flowway Near US41
Dry Season Volume Probability Curve (Nov 1 - May 31)

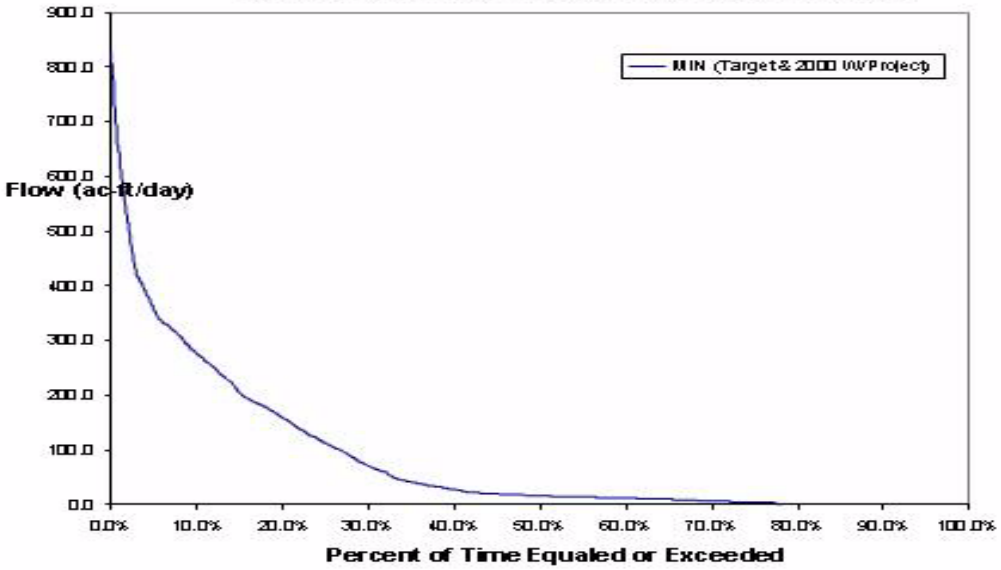


Figure 10.A. Simulated Surface Water Deliveries to Fakahatchee Bay From Fakahatchee Strand
Volume Probability Curve – 1988 Through 2000

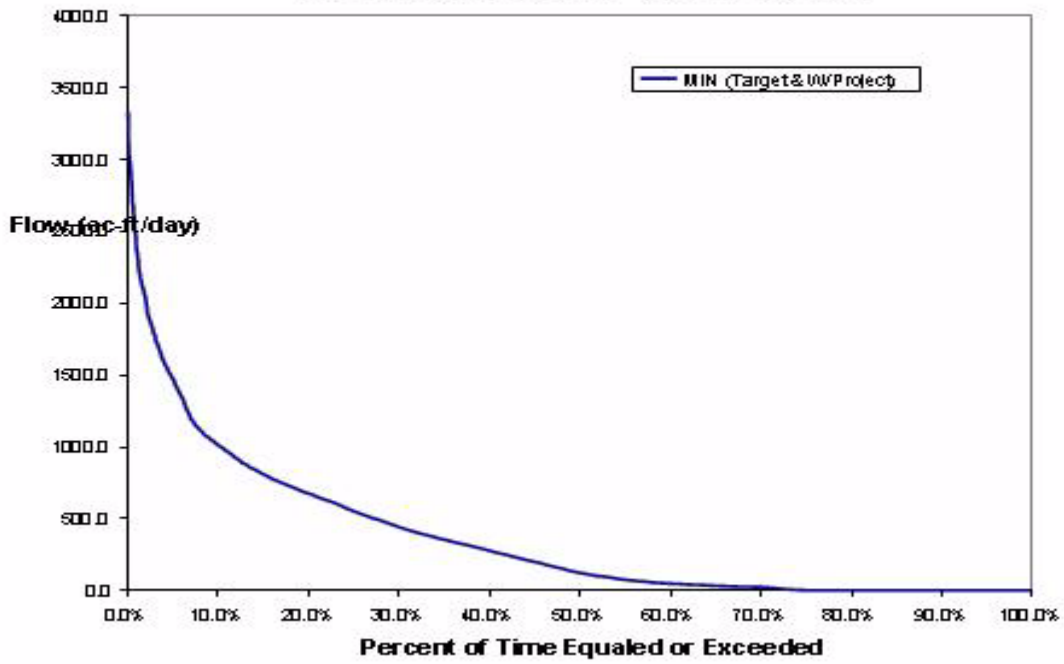


Figure 10. B. Simulated Surface Water Deliveries to Fakahatchee Bay from Fakahatchee Strand
Wet Season Volume Probability Curve (June 1- Oct 31)

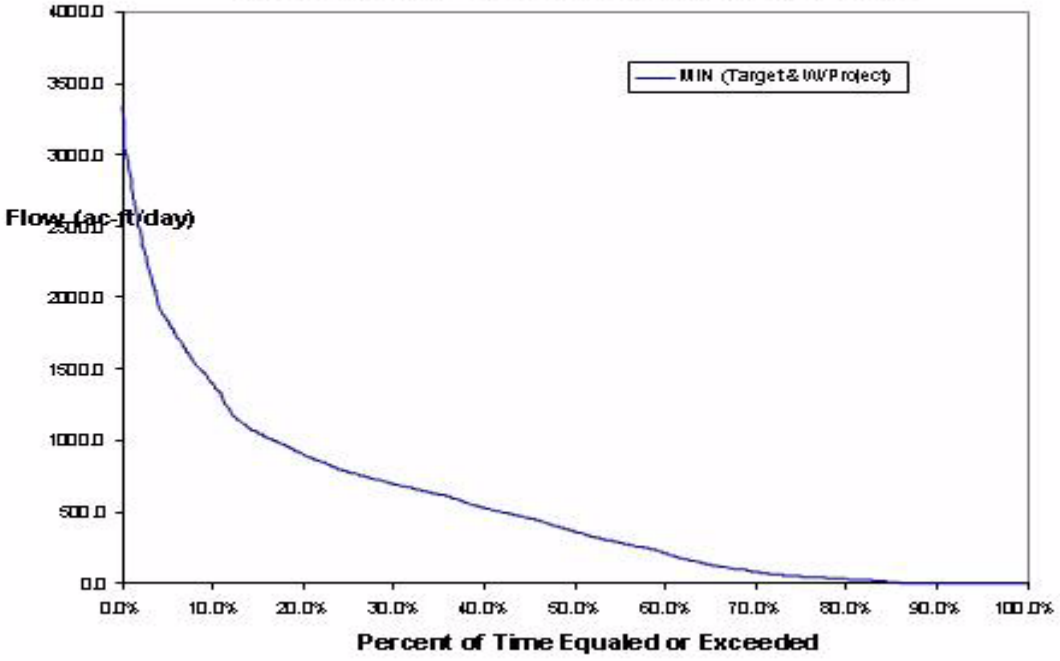
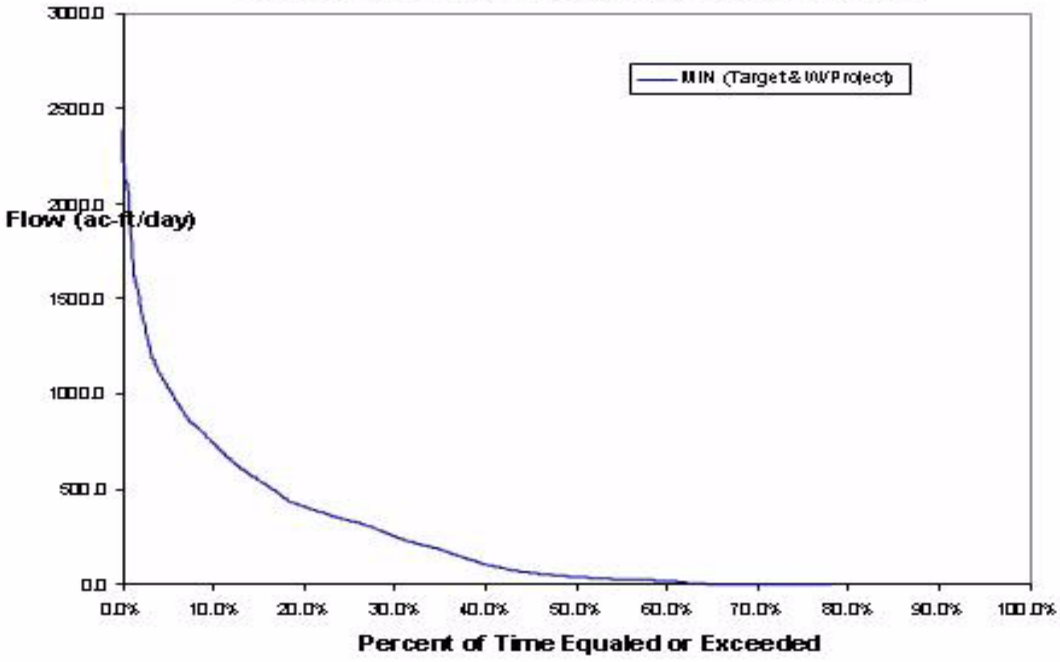


Figure 10.C. Simulated Surface Water Deliveries to Fakahatchee Bay from Fakahatchee Strand
Dry Season Volume Probability Curve (Nov 1 - May 31)



NAME OF PERSON ORIGINATING PROPOSED RULE: Wm. Scott Burns, Director, Everglades Water Supply Policy Implementation

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: South Florida Water Management District Governing Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 2, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 3, 2008

WATER MANAGEMENT DISTRICTS

South Florida Water Management District

RULE NOS.:	RULE TITLES:
40E-20.091	Publications Incorporated by Reference
40E-20.301	Conditions for Issuance of General Water Use Permits
40E-20.302	Types of General Water Use Permits
40E-20.331	Modification of General Water Use Permits

PURPOSE AND EFFECT: To incorporate requirements for protecting reserved water pursuant to Section 373.223(4), F.S. and to establish a water reservation for the Picayune Strand and Fakahatchee Estuary.

SUMMARY: The District proposes to amend the conditions for issuance of a general water use permit to include a condition that the proposed use not withdraw reserved water. A specific amendment to the No Notice Short Term Dewatering General Water Use Permit requiring water to be retained on site is also proposed to protect reserved water. For a summary of the proposed amendments to the criteria found in the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District" see the Notice of Proposed Rule for Chapter 40E-2, F.A.C., in this issue.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS:

Individuals and Entities Affected by the Proposed Rule

The proposed rule reserves water for protection of fish and wildlife in the Picayune Strand and the Fakahatchee Estuary in Collier County. The proposed rule will affect a subset of individuals and entities requesting water allocations from surface waters, the water table aquifer or the minimally confined portions of the lower Tamiami aquifer in western Collier County.

Water use permit applications proposing to withdraw waters that are reserved for the Picayune Strand or the Fakahatchee Estuary under the proposed rule would be denied. In this case, the applicant may choose to switch locations of water withdrawals to deeper portions of the subsurface within the aquifers not affected by the rule, reduce the proposed withdrawal, or move the proposed withdraw location farther away from the reservation water body or impacted canal. The number of individuals and entities potentially affected by this rule is not known but could include public supply utilities, industry, agricultural firms, golf course owners and entities that wish to maintain landscaping such as parks and schools located near the reservation water bodies or specified tributaries that deliver surface water that is proposed to be reserved under the rule. The geographic area affected by the proposed rule is limited to western Collier County. Existing land uses (platted single family homes, agricultural land holdings and publicly owned conservation lands) act to limit access to the surface waters within the reservation water bodies and canals where inflows are reserved.

The proposed rule set forth eight categories of consumptive uses that do not withdraw reserved water. If a consumptive use does not fall into one of these categories, the applicant must undertake modeling following the specific requirements set forth in the proposed criteria or other similarly acceptable alternative modeling evaluations to demonstrate that reserved water is not being withdrawn. Finally, the criteria provide that reduced or terminated permit impacts that result in increased inflows into the reservation water body may be allocated unless the Governing Board of the South Florida Water Management District determines that such allocation is inconsistent with the public interest.

Transactional Costs

A summary of the transactional costs is as follows.

• Existing legal uses on the effective date of the rule will have no transactional costs.

• Applicants for renewal of existing legal water uses on the effective date of the rule will have no transactional costs.

• New or modified uses that are not direct or indirect withdrawals will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

• Permit modifications that do not change the source, increase the allocation, or change withdrawal locations will have no transactional costs.

• Applicants for withdrawals from the Sandstone aquifer, Mid-hawthorn aquifer or the Floridan Aquifer systems will have no transactional costs.

• A proposed new use with a direct or indirect withdrawal and no greater impact, including changes in timing, on a reservation water body than the terminated or reduced permit existing on [effective date] within the same project site will have zero to minimal transactional costs, as the evaluations required under the proposed rule are also required under existing rule to provide reasonable assurance of compliance with other conditions for issuance under Rule 40E-2.301, F.A.C.

Costs of Modelling under Section 3.11.1.B.

An integrated surface and ground water transient model (transient hydrologic model) must be developed, calibrated and run for permit applications that are determined to have the potential of withdrawing reserved water quantities. Pursuant to Subsection 3.11.1.A.8., this group only includes applications for new or modified permits that have a direct or indirect withdrawal, as defined in the proposed rule.

This integrated transient hydrologic modeling is estimated to cost between $100,000 to $500,000, depending on the amount of data collection and modeling needed to determine whether the requested allocation will withdraw reserved water. The higher range of costs are associated with developing a model from scratch including developing regionalized input data sets for all model parameters. The lower range of costs consider time and cost savings associated with using existing regionalized input data sets when assembling a model. The District has developed two calibrated integrated transient models for the area (Picayune Strand PIR model and the LWC SAS Sub-Regional model). The input data sets are available to the public as public records and may be used by permit applicants in the development of the modeling required pursuant to the reservation rule.

If the results of the hydrologic modeling indicate that proposed new or modified withdrawals will withdrawal reserved water, the applicant may choose to develop an alternative water source, or otherwise modify the project so no reserved water will be withdrawn. The likely alternatives include aquifers located beneath the Lower Tamiami aquifer as specified in the rule. These include, in descending order, the Sandstone, Hawthorn Zone I / Lower Hawthorn, and Floridan aquifers.

For non-potable water uses, moving from a surface water source to the confined Lower Tamiami aquifer or the Sandstone aquifer will increase water supply costs by about $0.10 per 1,000 gallons of water produced. There is no significant cost difference between obtaining fresh water from the Water Table aquifer, the lower Tamiami aquifer, or the Sandstone aquifer. However, if these applicants are not able to obtain water from these sources, the increased cost associated with pumping and treating brackish water from the Hawthorn aquifer or the Floridan aquifer will increase significantly. The cost increase associated with going from the water table, lower Tamiami or Sandstone with not treatment to the Floridan Aquifer System with reverse osmosis treatment ranges from $3.42 per 1,000 gallons of water produced to $3.62 per 1,000 gallons depending on which aquifer is used.

For a public supply utility, the cost increase is not significant if the applicant moves from the Water Table aquifer or the Lower Tamiami aquifer to the Sandstone aquifer. However, if the applicant uses the Hawthorn or the Floridan aquifers, the cost increases by about $0.60 to $0.70 per 1,000 gallons. In this case, the degree of financial and economic impacts to the public supply utility would depend on the proportion of the utility's total water supply that comes from these sources.

Applicants for dewatering projects which retain the effluent water on-site, will not be impacted by the rule. If the retaining water on site is not feasible, the applicant will be required to demonstrate reserved water is not withdrawn. This could be done through modeling, or modifying the project (e.g. construction in the wet, establishing a hydraulic barrier between the dewatering site and the reservation water body, phased dewatering to reduce the impact e.t.c.). No specific cost estimates of these options have been compiled.

Cost to the District

The estimated one-time cost to the District to implement the proposed rule is $16,200. The estimated cost to the District to address each water use permit application that occurs within the area affected by this rule could be as much as $4,800 to $5,700 per applicant and $2,100 per dewatering permit for projects that involve extensive review. However, those projects that do not involve significant evaluations (such as renewals, modifications not involving reserved water, projects using alternative sources of supply etc.) will have minimal costs to the District.

Cost to Small Businesses, Small Cities and Small Counties

The City of Everglades will be affected by the proposed rule if it requests additional permitted water quantities from surface water or from the water table aquifer or from the lower Tamiami aquifer in western Collier County. There are likely to be several small businesses in Collier County that could be developed within the geographic area influenced by the rule. The potential costs associated with this rule are tied to the volume of water needed for the business, the location of the withdrawal, and the level of treatment needed.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 373.044, 373.113, 373.118 FS.

LAW IMPLEMENTED: 373.036, 373.042, 373.0421, 373.103(4), 373.118, 373.223, 373.229, 373.2295, 373.470, 373.1501, 373.1502 FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: February 12, 2009, 9:00 a.m.

PLACE: South Florida Water Management District, B-1 Auditorium, 3301 Gun Club Road, West Palm Beach, FL 33406

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 5 days before the workshop/meeting by contacting: South Florida Water Management District Clerk, (800)432-2045, ext. 2087 or (561)682-2087. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Scott Burns, Director, Everglades Water Supply Policy, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4224 or (561)682-4224, email: sburns@sfwmd.gov; Brenda Mills, Lead Planner, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 4208 or (561)682-4208, email: bmills@sfwmd.gov; Beth Lewis, Senior Supervising Attorney, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6343 or (561)682-6343, email: belewis@sfwmd.gov. For procedural questions contact Jan Sluth, Senior Paralegal, South Florida Water Management District, P. O. Box 24680, West Palm Beach, FL 33416-4680, (800)432-2045, ext. 6299 or (561)682-6299, email: jsluth@sfwmd.gov

THE FULL TEXT OF THE PROPOSED RULE IS:

40E-20.091 Publications Incorporated by Reference.

The "Basis of Review for Water Use Permit Applications within the South Florida Water Management District – _____ ~~October 14, 2008~~" is hereby published by reference and incorporated into this chapter. A current version of this document is available upon request.

Specific Authority 373.044, 373.113, 373.118 FS. Law Implemented 373.042, 373.0421, 373.103(4), 373.118, 373.223, 373.229 FS. History–New 8-14-02, Amended 8-31-03, 4-23-07, 9-13-07, 2-13-08, 10-14-08, _____.

(See Notice of Proposed Rule 40E-2.091, F.A.C., in this issue for proposed amendments to the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District")

40E-20.301 Conditions for Issuance of General Water Use Permits.

(1) In order to receive a general permit, permit renewal, or permit modification under this chapter, an applicant must provide reasonable assurances that the proposed water use:

(a) Will not cause harmful saline water intrusion;

(b) Will not harm offsite land uses;

(c) Will not cause harm to wetlands or other surface waters;

(d) Will not cause pollution of the water resources;

(e) Is otherwise a reasonable-beneficial use as defined in subsection 373.019(13), F.S., with consideration given to the factors set forth in subsection 62-40.401(2), F.A.C.

(f) Will not interfere with presently existing legal uses;

(g) Is in accordance with Section 373.2295, F.S., concerning interdistrict transfer of groundwater and Section 373.223(3), F.S., concerning water transport and use of groundwater or surface water across county boundaries.

(h) For uses with a recommended maximum allocation which exceeds 3 million gallons per month, makes use of a reclaimed water source in accordance with the criteria contained in the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District", incorporated by reference in Rule 40E-20.091, F.A.C.

(i) Is in accordance with the established minimum flows and levels and implementation provisions in Chapter 373, F.S., Chapters 40E-2 and 40E-8, F.A.C.; and

(j) Is consistent with Sections 373.016, 373.1501, 373.1502 and 373.036, F.S., and otherwise is consistent with the public interest as prescribed by Chapter 373, F.S., and this chapter.

(k) will not withdraw water reserved under Chapter 40E-10, F.A.C.

(2) In order to satisfy the conditions for permit issuance in subsection (1), the permit applicant must provide reasonable assurances that the criteria in the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District – April 23, 2007", incorporated by reference in Rule 40E-20.091, F.A.C., are met.

Specific Authority 373.044, 373.113, 373.118 FS. Law Implemented 373.036, 373.042, 373.103(4), 373.1501, 373.1502, ~~373.118,~~ 373.223, 373.229, 373.2295, 373.470 FS. History–New 8-14-02, Amended 8-31-03, 4-23-07, 2-13-08, _____.

40E-20.302 Types of General Water Use Permits.

(1) Standard General Water Use Permit – The use of water, which does not exceed a recommended maximum allocation of 15 million gallons per month (MGM), except as stated below, shall qualify for a Standard General Water Use Permit, provided the conditions for issuance in Rule 40E-20.301, F.A.C., are met. There are two types of Standard General Water Use Permits, as follows:

(a) Minor Standard General Water Use Permit, authorizes allocations of three (3) million gallons per month or less; and

(b) Major Standard General Water Use Permit, authorizes allocations greater than three (3) million and up to fifteen (15) million gallons per month, and includes a requirement under paragraph 40E-20.301(1)(h), F.A.C., and the applicable requirements in the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District", incorporated by reference in Rule 40E-20.091, F.A.C., that the permit applicant meet the requirements for use of reclaimed water. In addition the monitoring and reporting permit limiting conditions in Sections 4.0 and 5.0 of the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District", incorporated by reference in Rule 40E-20.091, F.A.C., are applicable.

(2) Dewatering General Water Use permit – The use of water in conjunction with short-term dewatering operations such as well pointing, utility construction, lake construction,

exploratory testing, and other minor uses; or in conjunction with a short-term Remedial Action Plan approved by the state or local agency having legal jurisdiction over such activities, shall qualify for a Dewatering General Water Use Permit, provided the conditions for issuance in Rule 40E-20.301, F.A.C., and the following requirement is met:

The proposed dewatering operation will not exceed a maximum of ten million gallons per day, with a maximum of eighteen hundred (1800) million gallons total pumpage and will not exceed a total duration of one year for the entire project.

(3) No-Notice Short-Term Dewatering General Water Use Permit – The use of water in conjunction with short-term dewatering operations, such as well pointing, utility construction, lake construction, exploratory testing, and other minor uses; or aquifer performance tests; or in conjunction with a short-term Remedial Action Plan approved by the state or local agency having legal jurisdiction over such activities, shall qualify for a No-Notice Short-Term Dewatering General Water Use Permit, provided the conditions for issuance in Rule 40E-20.301, F.A.C., and the following requirements are met:.

(a) The proposed dewatering operation will not exceed a maximum of five (5) million gallons per day, with a maximum of one hundred (100) million gallons total pumpage and will not exceed a total duration of 90 days for the entire project, except for linear construction projects, such as roads, utilities, and pipelines, which may have a rolling 90-day duration in which the dewatering operation at the end of each 90-day period occurs more than 1 mile from the location at the beginning of each 90-day period; and

(b) To demonstrate compliance paragraph 40E-20.301(1)(k), F.A.C., all water shall be retained onsite.

Specific Authority 373.044, 373.113, 373.118 FS. Law Implemented 373.042, 373.0421, 373.103(4), 373.118, 373.219, 373.223 FS. History–New 9-3-81, Amended 12-1-82, Formerly 16K-2.031(1), 16K-2.032(1)(b), Amended 2-24-85, 3-29-87, 7-26-87, 4-20-94, 7-11-96, 4-9-97, 12-10-97, 11-4-01, 8-14-02, 8-31-03, 4-23-07, 2-13-08,_____.

40E-20.331 Modification of General Water Use Permits.

(1) A permittee shall apply to the District for approval of any modification of an unexpired general water use permit pursuant to Section 373.239, F.S., and Rule 40E-1.609, F.A.C.

(2) Applications for modification except for modifications issued pursuant to subsection (3) shall contain the information required in Rule 40E-20.101, F.A.C., will be evaluated using the conditions and requirements specified in Rules 40E-20.301 and 40E-20.302, F.A.C., and will be subject to the limiting conditions specified in Rule 40E-20.381, F.A.C. Modifications shall be approved if the conditions and requirements in Rules 40E-20.301 and 40E-20.302, F.A.C., are met.

(3)(a) Modification of an existing general water use permit shall be approved by letter, provided the permit is in compliance with all applicable limiting conditions and the modification request:

1. Does not exceed the applicable general permit allocation limitations in Rule 40E-20.302, F.A.C.;

2. Does not result in a requested permit duration which exceeds the expiration date of the existing permit, except that when the permit duration is based upon the current lease expiration date, the permit duration may be extended by letter modification to the new lease date, but shall not exceed the applicable permit duration pursuant to subsection 40E-20.321(2), F.A.C.;

3. Does not potentially interfere with any presently existing legal use of water, cause harm to wetlands or other surface waters, harmful saltwater intrusion or pollution of the water resources, harm to offsite land uses, <u>does not withdraw water reserved under Chapter 40E-10, F.A.C.</u> or does not otherwise raise issues requiring a Staff determination of whether harm to the water resources would occur pursuant to the "Basis of Review for Water Use Permit Applications within the South Florida Water Management District", incorporated by reference in Rule 40E-20.091, F.A.C.;

4. Does not change the permitted withdrawal source; and

5. Does not result in a modification of the permit which must be approved by the Governing Board pursuant to Section 373.239(2), F.S.

(b) The time frames set forth in Rule 40E-1.603, F.A.C., shall apply to the processing of applications for letter modifications.

Specific Authority 373.044, 373.113 FS. Law Implemented 373.223, 373.229, 373.239 FS. History–New 4-20-94, Amended 7-11-96, 4-9-97, 12-10-97, 8-14-02, 8-31-03, 4-23-07, 2-13-08,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Wm. Scott Burns, Director, Everglades Water Supply Policy Implementation

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: South Florida Water Management District Governing Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 2, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 3, 2008

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Water and Wastewater Treatment Plant Operators

RULE NOS.:	RULE TITLES:
61E12-41.002	Definitions
61E12-41.003	Qualifications for Operator Certification
61E12-41.004	Applications for Certification from Persons with Actual Experience
61E12-41.005	Examinations; Forms for Certification
61E12-41.006	Operator Certification
61E12-41.007	Renewal of Operator Certificates
61E12-41.009	Denial of Application or Renewal of Certificates; Notice of Denial or Renewal
61E12-41.010	Duties of Operators
61E12-41.011	Fees
61E12-41.013	Grounds for Disciplinary Proceedings
61E12-41.014	Citations
61E12-41.016	Suspension and Revocation of Operator Certificates
61E12-41.017	Disciplinary Guidelines; Aggravating and Mitigating Circumstances
61E12-41.018	Actual Experience for Operator Certification

PURPOSE AND EFFECT: The purpose and effect of the proposed rule amendment will be to repeal rules the Department no longer has authority to enforce.

SUMMARY: These are outdated rules governing water and wastewater treatment plant operators.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 455.213, 468.545 FS.

LAW IMPLEMENTED: 455.217, 468.542, 468.543, 468.545, 468.547, 468.548, 468.549, 468.550, 468.552 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Patricia Nelson, Assistant General Counsel, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399, (850)488-0062

THE FULL TEXT OF THE PROPOSED RULES IS:

61E12-41.002 Definitions.

Specific Authority 455.213, 468.545 FS. Law Implemented 120.52(9), 468.542, 468.545, 468.548 FS., Section 4, Chapter 92-75, Laws of Florida. History–New 11-2-93, Amended 7-5-94, 7-12-95, Repealed _____.

61E12-41.003 Qualifications for Operator Certification.

Specific Authority 468.545, 468.548 FS. Law Implemented 468.543, 468.548 FS., Section 4, Chapter 92-75, Laws of Florida. History–New 11-2-93, Amended 7-5-94, 7-15-96, Repealed _____.

61E12-41.004 Applications for Certification from Persons with Actual Experience.

Specific Authority 468.545 FS. Law Implemented 468.545, 468.548 FS., Section 4, Chapter 92-75, Laws of Florida. History–New 11-2-93, Amended 7-5-94, Repealed _____.

61E12-41.005 Examinations; Forms for Certification.

Specific Authority 468.545 FS. Law Implemented 455.217(2), 468.545, 468.547, 468.548 FS. History–New 11-2-93, Amended 5-29-96, Repealed _____.

61E12-41.006 Operator Certification.

Specific Authority 468.545 FS. Law Implemented 468.545, 468.548 FS., Section 4, Chapter 92-75, Laws of Florida. History–New 11-2-93, Repealed _____.

61E12-41.007 Renewal of Operator Certificates.

Specific Authority 468.545, 468.549 FS. Law Implemented 468.545, 468.547, 468.549 FS. History–New 11-2-93, Amended 7-15-96, Repealed _____.

61E12-41.009 Denial of Application or Renewal of Certificates; Notice of Denial or Renewal.

Specific Authority 468.545, 468.548, 468.549 FS. Law Implemented 455.227, 468.545, 468.548, 468.549, 468.550, 468.552 FS. History–New 11-2-93, Repealed _____.

61E12-41.010 Duties of Operators.

Specific Authority 468.545, 468.552 FS. Law Implemented 468.541, 468.543, 468.545, 468.552 FS., Section 4, Chapter 92-75, Laws of Florida. History–New 11-2-93, Repealed _____.

61E12-41.011 Fees.

Specific Authority 468.545, 468.547 FS. Law Implemented 119.07(1)(a), (b), 455.203(5), 455.217(2), 455.219(6), 455.225(4), 468.547, 468.548, 468.549, 468.550, 468.552 FS. History–New 11-2-93, Amended 7-5-94, 7-12-95, 7-15-96, Repealed _____.

61E12-41.013 Grounds for Disciplinary Proceedings.

Specific Authority 455.224, 468.552 FS. Law Implemented 455.227, 468.541, 468.543, 468.545, 468.551 FS. History–New 11-2-93, Amended 7-5-94, Repealed _____.

61E12-41.014 Citations.

Specific Authority 455.224, 455.225, 468.541, 468.543 FS. Law Implemented 455.224 FS. History–New 11-2-93, Repealed _____.

61E12-41.016 Suspension and Revocation of Operator Certificates.

Specific Authority 468.552 FS. Law Implemented 468.541, 468.551, 468.552 FS. History–New 11-2-93, Repealed _____.

61E12-41.017 Disciplinary Guidelines; Aggravating and Mitigating Circumstances.

Specific Authority 468.545 FS. Law Implemented 468.551, 468.552 FS. History–New 11-2-93, Repealed _____.

61E12-41.018 Actual Experience for Operator Certification.

Specific Authority 468.545, 468.548 FS. Law Implemented 468.548 FS. History–New 11-2-93, Amended 7-15-96, Repealed _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Patricia Nelson, Assistant General Counsel, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399, (850)488-0062

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Charles W. Drago

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 3, 2008

DEPARTMENT OF ENVIRONMENTAL PROTECTION

Notices for the Department of Environmental Protection between December 28, 2001 and June 30, 2006, go to http://www.dep.state.fl.us/ under the link or button titled "Official Notices."

DEPARTMENT OF HEALTH

Board of Medicine

RULE NO.: RULE TITLE:
64B8-51.001 Manner of Application

PURPOSE AND EFFECT: The Board proposes the rule amendment to incorporate the updated application form.

SUMMARY: The rule amendment will incorporate the updated application form.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 478.43(1), (4) FS.

LAW IMPLEMENTED: 478.45 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allen Hall, Executive Director, Electrolysis Council/MQA, 4052 Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3255

THE FULL TEXT OF THE PROPOSED RULE IS:

64B8-51.001 Manner of Application.

(1) All persons applying for licensure as an electrologist shall submit a signed application to the Executive Director of the Council on forms provided by the Council and approved and incorporated herein by reference by the Board as Form DH-MQA 1164, 11/08, incorporated by reference ~~DOH/MQA/EO APP/REV-04/03~~, ~~entitled "Application for Electrologist Licensure", effective 2-15-04~~, which can be obtained from the Council. The initial application must be accompanied by the application fee, as set forth in Rule 64B8-51.007, F.A.C.

(2) through (3) No change.

Specific Authority 478.43(1), (4) FS. Law Implemented 478.45 FS. History–New 5-31-93, Formerly 21M-76.001, Amended 11-10-93, Formerly 61F6-76.001, Amended 5-29-96, Formerly 59R-51.001, Amended 12-23-97, 5-28-00, 8-9-01, 2-15-04, 10-31-05, 2-11-08, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Electrolysis Council

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Medicine

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 4, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: December 12, 2008

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NOS.: RULE TITLE:
64F-12.001 General Regulations; Definitions

PURPOSE AND EFFECT: The Department proposes to amend the rule to provide a definition for statutory and rule terms and define or revise the terms. The changes will make the definitions set forth in this rule section applicable to both Chapter 64F, Florida Administrative Code and to Chapter 499, Florida Statutes.

SUMMARY: The rule will define or revise the terms "affiliated group", "distribution point", "limited quantities", "intra-company transfer", "principal address", "propagation" and "specific drug".

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 499.024, 499.025(5), 499.01(6), 499.0121(6), 499.0122(2), 499.012(5) (12), 499.013(3), 499.01(2)(g), 499.014(5), 499.03(4), 499.05, 499.701 FS.

LAW IMPLEMENTED: 499.002, 499.003, 499.004, 499.005, 499.0051, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.04, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.055, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.701, 499.71, 499.75 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.PH., Director, Drugs Devices and Cosmetics Program 4052 Bald Cypress Way, Mail Bin C-04, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

64F-12.001 General Regulations; Definitions.

(1) A word or phrase defined in 21 U.S.C. ss. 301 et seq. or federal regulations promulgated thereunder in Title 21 Code of Federal Regulations (C.F.R.), (as of 10/1/03) which are incorporated by reference herein, shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S. or Rule Chapter 64F-12, F.A.C.

(2) In addition to definitions contained in Sections 499.003, 499.012(1), 499.0121(6), ~~499.0122(1),~~ 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S. and to Rule Chapter 64F-12, F.A.C.:

(a) "Administer" – means the obtaining and giving of a single dose of drugs by a legally authorized person to a patient for his consumption.

(b) "Affiliated group" – for purposes of this rule chapter, means the definition of the term set forth at Section 499.003(2), F.S. ~~the definition set forth in Section 1504 of the Internal Revenue Code (as of April 24, 2003) which is incorporated by reference herein, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:~~

~~1. Discloses to the department the names of all its members; and~~

~~2. Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored. For an affiliated group to qualify under Section 499.0121(6)(f)1., F.S., such affiliated group must also meet all the conditions specified by Section 499.0121(6)(f), F.S.~~

(c) "Authorized absence" – means, for purposes of Section 499.012(16)~~(11)~~(d), F.S., the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under Section 499.051, F.S., at the time of the inspection, the absence of the designated representative for a period not to exceed 60 calendar days for situations such as: the birth of the employee's child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the employee is needed to care for a family member (child, spouse or parent) with a serious health condition; or the employee's own serious health condition makes the employee unable to perform the functions of the designated representative.

(d) "Authorized recipient" – means a person permitted by or otherwise authorized by Chapter 499, F.S., to purchase, receive or possess prescription drugs; a pharmacy licensed by Chapter 465, F.S., except a Class I Institutional Pharmacy since it is only authorized to possess dispensed prescription drugs and medical oxygen for administration to its patients; a practitioner licensed by Florida law to purchase and receive prescription drugs; or a person who is authorized by the law where the delivery occurs to purchase, receive or possess prescription drugs. A licensed ship captain or first officer for a vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government is an authorized recipient for prescription drugs intended solely for emergency medical purposes, provided the prescription drugs are delivered by the wholesaler directly to the ship.

(e) "Broker" – means a person participating in the wholesale distribution of a prescription drug that buys or ~~and~~ sells the drug but does not take physical possession of ~~such that~~ the drug ~~is "sold to" the broker and "shipped to" a third party~~.

(f) "Change in Ownership" – means a majority (more than 50%) of the ownership or controlling interest changes. A change in ownership occurs when there has been any change in a partnership amounting to more than 50% of the ownership or controlling interest. For a publicly traded corporation, the changing of officers or directors is not a change in ownership nor is the change in ownership of a parent company provided that such change does not result in more than a 50% change in the ownership or controlling interest of any permitted establishment.

(g) "Chief Executive Officer" – means the owner or the highest ranking official of a corporation, company, or business.

(h) "Directly from the manufacturer" – means:

1. For ~~the~~ purposes of the ~~a~~ pedigree document as defined at Section 499.01212(2)(b) ~~499.003(31)(b)~~, F.S., the manufacturer of the specific unit of the prescription drug

invoiced and sent that specific unit of the prescription drug directly to the purchasing wholesale distributor or its wholly owned subsidiary.~~, or~~

~~2. For the purposes of Section 499.0121(6)(d)5., F.S., the manufacturer of the prescription drug ships the specific unit of the prescription drug directly to the person authorized by Section 499.0121(6)(d)5., F.S., to receive the specific unit of the prescription drug.~~

(i) "Distribution Point" as used in the definition of "manufacturer" in Section 499.003(31), F.S. means: an establishment, i.e., a place of business at one general physical location from which prescription drugs are shipped, but not sold, into commerce.

(j)~~(i)~~ "Electronic signature" – means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

(k)~~(j)~~ "Established safe and effective indication" – means any indication that has been approved as safe and effective by the FDA, which is generally recognized as safe and effective under conditions established by the FDA, or which is otherwise in compliance with FDA's regulations.

(l)~~(k)~~ "FDA" – means the United States Food and Drug Administration.

(m)~~(l)~~ "Intracompany transfer" – means any transaction or transfer between any parent, division or subsidiary wholly owned by a corporate~~, pursuant to Section 499.003(31)(b), F.S., a distribution of a specific unit of a prescription drug between two establishments wholly owned and operated by the same business~~ entity.

(n)~~(m)~~ "Legend Device or Restricted Device" – means any device which can be dispensed only by the prescription or order of a licensed practitioner and which device on its label bears either the words: "Caution: Federal Law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any practitioner licensed by law to use or prescribe the device; "Caution: Federal Law prohibits dispensing without prescription; "Rx Only;" or "Caution: Florida Law prohibits dispensing without prescription."

(o) "Limited quantities", for purposes of the licensure exemption described at Section 499.012(2)(c)3., F.S., for research and development being performed for a specific prescription drug a limited quantity is the amount of an active pharmaceutical ingredient required to perform the research and development for a period no longer than 30 days. No more than two transactions for receipt of an active pharmaceutical ingredient for a specific prescription drug may occur within a 30 day period.

(p)~~(n)~~ "Pedigree" – means a document that satisfies the requirements of Section 499.01212(a) or (b), ~~499.003(31)(a) or (b),~~ F.S., as applicable, and the applicable rule requirements of subsection 64F-12.012(3), F.A.C., and any forms adopted therein.

(q)~~(o)~~ "Point of origin" – means the location from which the manufacturer transfers title, and the location from which the manufacturer transfers possession, if different, of the specific unit of the prescription drug being transferred or sold.

(r)~~(p)~~ "Practitioner" means a person who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes.

(s) "Principal Address" means for all establishments permitted by or required by law to be permitted by the Department, the full physical address of the establishment. For purposes of invoicing a purchaser of drugs, devices or cosmetics, a post office box number can be used as an additional address, in addition to the full physical address on the invoice.

(t)~~(q)~~ "Product" – anything produced or made either naturally or artificially.

~~(r) "Propagation" of a drug – means, as used under the definition of "manufacture" at Section 499.003(27), F.S., for purposes of permitting under Section 499.013, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site.~~

(u)~~(s)~~ "Provides prescription services to the public" – means, for the purposes of the retail pharmacy wholesaler permit, holding the pharmacy out to the public through prominently displayed pharmacy signs on the exterior of the building and having adequate inventory on hand to fill a variety of prescriptions for a variety of medical conditions that would be required by the public generally.

(v)~~(t)~~ "Readily available" and "readily retrievable" mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request (unless the permitted address is not within the state in which case a 48 hour timeframe is available for producing records). Required records that are kept by automatic data processing systems or other electronic or

mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

(w)~~(u)~~ "Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" means:

1. Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 to bottles of 100.

2. Altering a manufacturer's package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.

3. Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:

a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or

b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

(x)~~(v)~~ "Rx" – means prescription.

(y)~~(w)~~ "Sale" – includes any transfer of title or ownership, whether by barter, exchange ~~or~~ gift or in some other manner.

(z)~~(x)~~ "Separate and distinct cosmetic product" – means a cosmetic product for that establishment which is, or will be sold, distributed, or given away. The adding of color, flavor, or scents does not make a separate and distinct cosmetic product for each variation.

(aa)~~(y)~~ "Separate and distinct device product" – means a device product in its finished form for that manufacturer which is, or will be sold, distributed, or given away. The function or use of the device determines whether a device is separate and distinct.

(bb)~~(z)~~ "Separate and distinct drug product" – means a drug product in the finished form and strength for that manufacturer which is, or will be sold, distributed or given away.

(cc)~~(aa)~~ "Specific unit of the ~~a~~ prescription drug" – means the individual saleable unit of a specific prescription drug being transferred or sold, which is capable of being serialized to contain its own serial number, which drug is identified by name, strength, dosage form, container size, and lot number.

~~(bb) "Specified drug" means all dosage forms, strengths and container sizes of the following prescription drugs:~~

~~1. Bextra (valdecoxib);~~

~~2. Celebrex (celecoxib);~~

~~3. Combivir (lamivudine/zidovudine);~~

~~4. Crixivan (indinavir sulfate);~~

~~5. Diflucan (fluconazole);~~

~~6. Epivir (lamivudine);~~

~~7. Epogen (epoetin alfa);~~

~~8. Gamimune (globulin, immune);~~

~~9. Gammagard (globulin, immune);~~

~~10. Immune globulin;~~

~~11. Lamisil (terbinafine);~~

~~12. Lipitor (atorvastatin calcium);~~

~~13. Lupron (leuprolide acetate);~~

~~14. Neupogen (filgrastim);~~

~~15. Nutropin AQ (somatropin, e coli derived);~~

~~16. Panglobulin (globulin, immune);~~

~~17. Procrit (epoetin alfa);~~

~~18. Retrovir (zidovudine);~~

~~19. Risperdal (risperidone);~~

~~20. Rocephin (ceftriaxone sodium);~~

~~21. Serostim (somatropin, mannalian derived);~~

~~22. Sustiva (efavirenz);~~

~~23. Trizivir (abacavir sulfate/lamivudine/zidovudine);~~

~~24. Venoglobulin (globulin, immune);~~

~~25. Viagra (sildenafil citrate);~~

~~26. Videx (didanosine);~~

~~27. Viracept (nelfinavir mesylate);~~

~~28. Viramune (nevirapine);~~

~~29. Zerit (stavudine);~~

~~30. Ziagen (abacavir sulfate);~~

~~31. Zocor (simvastatin);~~

~~32. Zofran (ondansetron);~~

~~33. Zoladex (goserelin acetate); and~~

~~34. Zyprexa (olanzapine).~~

(dd)~~(cc)~~ "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of 1/1/01 in Title 21 Code of Federal Regulations, Parts 210, 211, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in Rule 64F-12.010, F.A.C.

(ee)~~(dd)~~ "Unapproved new drug" – means any drug which has not been approved or otherwise authorized for use under the federal act, 21 U.S.C. ss. 301 et seq., and the regulations promulgated thereunder or which does not have a Notice of Claimed Investigational Exemption on file with the United States Food and Drug Administration.

(ff)~~(ee)~~ "Usual course of business as common carriers" – means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes:

1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR s. 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and,

2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 64F-12.012(1), (2), F.A.C., apply to all distributions of prescription drugs under this sub-sub paragraph. In all such distributions to commercial airlines, the recipient's license number shall be the registration number assigned to the carrier by the Federal Aviation Administration.

(gg)~~(ff)~~ "Valid client-veterinarian relationship" – means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

(hh)~~(gg)~~ "Verifiable account" – means a number issued by the manufacturer to a wholesale distributor ~~wholesaler~~ when the wholesale distributor ~~wholesaler~~ sets up an account with the manufacturer for the purchase of a prescription drug from that manufacturer that uniquely identifies the wholesale distributor ~~wholesaler~~ and that is to be used on a recurring basis.

(ii)~~(hh)~~ "Wholesale distribution" – means distribution of prescription drugs to persons other than a consumer or patient as set forth in Section 499.003(54) ~~499.012(1)(a)~~, F.S.

(jj)~~(ii)~~ "Wholesale distributor" ~~"Wholesaler"~~ – means a person who engages in the wholesale distribution of a prescription drug.

(kk)~~(jj)~~ "Written agreement" means any type of written correspondence or documentation to establish an account for ongoing sales of prescription drugs by the manufacturer to that wholesaler.

Specific Authority 499.003(31), 499.024, 499.025(5), 499.01(6), 499.0121(6), 499.0122(2), 499.012(12), 499.013(3), 499.014(5), 499.03(4), 499.05 FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History–New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06, 12-27-07, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston, R.Ph.

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Dr. Ana Viamonte Ros

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 23, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 18, 2008

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO.:	RULE TITLE:
64F-12.012	Records of Drugs, Cosmetics and Devices

PURPOSE AND EFFECT: The Department proposes to revise the rule language regarding pedigree requirements to be compliant with Chapter 499, F.S. (2008).

SUMMARY: The rule revisions will clarify the pedigree requirements for normal distribution chain direct purchase pedigrees, alternative pedigrees, returns and emergency distributions.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS.

LAW IMPLEMENTED: 499.002, 499.01, 499.003, 499.005, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.Ph., Executive Director, Drugs Devices and Cosmetics Program, 4052 Bald Cypress Way, Mail Bin C04, Tallahassee, Florida 32399, (850)245-4292

THE FULL TEXT OF THE PROPOSED RULE IS:

64F-12.012 Records of Drugs, Cosmetics and Devices.

(1)(a) Records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component. A complete audit trail includes records which document each transaction or step in the receipt, manufacture, shipping, transfer, or other steps in the channel of trade of that person, whether or not physical possession or handling of the product or component occurs. At a minimum, records shall consist of invoices from the supplier or source which documents acquisition of each product by the person and invoices of sale or other transfer by the person to the recipient. Retail sales transactions to the consumer of over-the-counter drugs, non-restricted devices, or cosmetics are exempt from the requirements of this rule. Additional recordkeeping is required for persons permitted by the department as further stated in this rule.

(b) A person engaged in the distribution of drugs, devices, or cosmetics is not required to maintain documentation from a common carrier that the designated recipient received the product shipped; however, the person must obtain such documentation from the common carrier and make it available to the department upon specific request of the department.

(2) Any person engaged in the manufacture of prescription drugs, the wholesale distribution of prescription drugs, or otherwise receiving or distributing prescription drugs must maintain records as follows:

(a) For each step in the channel of trade, records containing the information required by Section 499.0121(6)(a), F.S., and the Florida permit or license number which authorizes the source to possess and transfer prescription drugs in or into Florida must appear on one document, provided that, the financial documentation required by Section 499.0121(6)(a)5., F.S. does not have to be included on the same document so long as it is included on the invoice or other billing document for the transaction. If delivery of prescription drugs is made to a person other than the purchaser, the name, address or location where the prescription drugs are delivered, and the state license, permit or registration number for that location must be included also.

(b) The state permit or registration number of the purchaser may be omitted if the prescription drugs are exported; but a validated airway bill, bill of lading or other appropriate documentation must be maintained to evidence the exportation of the product.

(c) Invoices must reflect the amount billed per prescription drug product.

(d) Records to document the distribution of prescription drugs required by Section 499.0121(6), F.S., and this rule are to be created during the transaction (i.e., at the time of order, receipt, processing, picking or shipping) and not retroactively created. A pharmacy or other person authorized to possess prescription drugs that transfers prescription drugs to an establishment performing reverse distribution services or destruction activities must prepare or have prepared an inventory or other record of the prescription drugs so transferred prior to the prescription drugs leaving the premises. In addition to the name, address, and license number of the sender and the name, address, and license number of the receiving establishment, the record must include the elements set forth in paragraph 64F-12.023(3)(a), F.A.C.

(e) Inventory. A complete and accurate record of all stock of prescription drugs on hand must be made annually available by establishments permitted under Chapter 499, F.S. A physical inventory must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis. Significant inventory discrepancies must be investigated and handled in accordance with the written policies and procedures of the establishment. In addition, no later than July 17, 2006, each wholesale distributor shall submit to the department an inventory of drugs it has on hand as of June 30, 2006.

(f) Inventory existing as of June 30, 2006. A wholesale distributor permitted under Ssection 499.012, F.S. that has purchased a prescription drug on or before close of business June 30, 2006 without the pedigree required by Ssection 499.0121(6)(d), F.S. (2006) may distribute such drug provided the wholesale distributor submits to the department an inventory of such drugs no later than July 17, 2006, conforming to paragraph (2)(e) above and provided further that such drugs are otherwise in compliance with the provisions of Sections ~~ss.~~ 499.001 through 499.081, F.S. Inventories shall be submitted to the Department in written form, email, facsimile, or electronic media excluding a web page. The Department will consider the submittal to be a trade secret as defined by Sections ~~s.~~ 812.081(1)(c), F.S., provided that the sending wholesale distributor complies with the requirements of subsections 64F-12.021(1) and (2), F.A.C.

(3) Pedigrees; Normal Distribution Chain Direct Purchase Pedigree; Alternative Pedigree. In order to satisfy the pedigree requirements in Section 499.01212(2), F.S., the appropriate one of the two pedigree documents defined in Section 499.01212(2), F.S., must be used. They are the "Direct Purchase Pedigree" document, which is defined at Section 499.01212(2)(a), F.S., and the "Alternative Pedigree" document, which is defined at Section 499.01212(2)(b), F.S., and also contains the elements in the forms approved by the Department in this rule section.

(a) Normal Distribution Chain Direct Purchase Pedigree.

1. The direct purchase pedigree is the pedigree document defined in Section 499.01212(2), F.S. It is statement in written or electronic form, accurately confirming that the wholesale distributor or its wholly owned subsidiary who purchases and receives the specific unit of the prescription drug being distributed, purchased and received the specific unit of the prescription drug directly from the manufacturer of the drug. The direct purchase pedigree document can be used to satisfy the requirements of Section 499.01212(2), F.S., only if the wholesale distributor or wholly owned subsidiary distributes that specific unit of the prescription drug that it purchased and received directly from the manufacturer, to a chain pharmacy warehouse as described at Section 499.003(7), F.S. or to a person authorized to purchase a prescription drug for the purpose of administering or dispensing such drug ("purchaser") in one of two ways:

a. The subject wholesale distributor or wholly owned subsidiary distributes the prescription drug directly to the purchaser; or,

b. The subject wholesale distributor or wholly owned subsidiary distributes the prescription drug indirectly to the purchaser through the use of no more than two intracompany transfers.

2. In order to qualify for use of the direct purchase pedigree the wholesale distributor and its wholly owned subsidiary who purchases and receives the specific unit of the prescription drug directly from the manufacturer must accurately provide the statement and information required by Section 499.01212(2)(a), F.S. on the pedigree document. The wholesale distributor and its wholly owned subsidiary shall maintain and make available to the department the documentation required by Section 499.01212(2)(a), F.S. as well as the documentation required by Section 499.0121(6), F.S. and this rule chapter.

3. The direct purchase pedigree shall be provided to every recipient of the prescription drug, except for a patient or consumer, who receives the specific unit of the prescription drug directly or indirectly, from the wholesale distributor or its wholly owned subsidiary who purchases and receives the specific unit of the prescription drug directly from the manufacturer. In a wholesale distribution of a prescription drug, the direct purchase pedigree document shall not contain any reference to a prescription drug that is not eligible for use of the direct purchase pedigree to satisfy the requirements of Section 499.01212(2), F.S., unless the prescription drug not qualifying for distribution through use of the direct purchase pedigree is clearly identified on the pedigree document as not having been purchased and received directly from the manufacturer of the drug. For any distribution of prescription drugs in or into this state, the direct purchase pedigree shall not be used unless all distributions, including transfer of title and transfer of possession of a prescription drug from the manufacturer to a pharmacy or other person authorized to prescribe, administer or dispense prescription drugs, are eligible for use of the direct purchase pedigree to satisfy the requirements of Section 499.01212(2), F.S.

(b) Alternative Pedigree. The alternative pedigree is the pedigree described in Section 499.01212(2)(b), F.S., in this rule section and in the forms adopted thereunder. For all wholesale distributions that require a pedigree pursuant to Section 499.01212(2)(b), F.S., the alternative pedigree must be used for all distributions of prescription drugs that are not eligible for use of the direct purchase pedigree. The forms approved by the department for this pedigree are:

1. Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)", Form DH 2129, effective July 2006, which is incorporated by reference herein, or an electronic record that contains all of the elements of Form DH 2129, for the wholesale distribution of a prescription drug; or,

2. Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)", DH Form 2135, effective July 2006, which is incorporated by reference herein, or an electronic record that contains all of the elements of Form DH 2135.

3. A repackager must use either Form DH 2135 or an electronic record that contains all of the elements of Form DH 2135. A wholesale distributor that further distributes a repackaged prescription drug must include in the pedigree the information related to the repackaged drug contained in Form DH 2135 or the electronic record that contains all of the elements of Form DH 2135.

4. The alternative pedigree must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

(c) A copy of the pedigree must be maintained by each wholesale distributor required to prepare or furnish a pedigree and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesale distributor required to prepare or furnish the pedigree; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesale distributor serves as the repository of its customer's pedigree, the wholesale distributor must specify on the customer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each

prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period. No provision of this rule subsection shall be construed to relieve any wholesale distributor from any requirement imposed by any provision of Chapter 499, Part I, Florida Statutes to provide the recipient of a prescription drug in a wholesale distribution with a complete and accurate pedigree paper in a timely manner. No provision of this rule sub-section shall be construed to relieve any recipient of a prescription drug from any requirement imposed by any provision of Chapter 499, Part I, F.S. for the recipient of a prescription drug in a wholesale distribution to receive a pedigree paper in a timely manner.

(d) Each alternative pedigree must contain a signature that meets the requirements of DH Form 2129 or 2135 as applicable. An electronic signature may be used on a pedigree.

(e) An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices.

Additional information to the information required by these rules and Section 499.01212(2)(a) or (b), as applicable, may be provided on a pedigree so long as the additional information does not detract from or confuse the history of the distribution of the drug or fail to clearly specify each prescription drug identified on a direct purchase pedigree document that is not eligible for use of the direct purchase pedigree pursuant to the requirements of Sections 499.01212(2)(a), 499.003(33), F.S. and this rule section.

(f) Each person required by Section 499.01212, F.S. to receive the pedigree must maintain it. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesale distributor providing the pedigree paper. No provision of this rule subsection shall be construed to require any person who is exempted by Section 499.01212(3), F.S., to pass a pedigree.

(g) Returns.

1. When a distribution of a prescription drug by a wholesale distributor to an authorized recipient is the result of a mistake in ordering or shipment, the return of that shipment by the authorized recipient to the wholesale distributor need not be reflected in the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within seven calendar days after the date of receipt of the original shipment:

a. The authorized recipient ships the specific unit of the prescription drug back to the wholesale distributor from which that specific unit was purchased; or

b. The authorized recipient transmits a documented communication to the wholesale distributor from which the prescription drug was purchased stating the authorized recipient's intent to return the shipment in accordance with the wholesale distributor's prescribed written policies and procedures and the wholesale distributor communicates authorization for return of the product.

2. Any returns to a wholesale distributor by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in the pedigree paper trail for any further distributions of the returned drug product to the extent required by Section 499.01212(2)(b), F.S.

3. An authorized recipient that returns a shipment to the wholesale distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product:

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesale distributor (including the corresponding sales invoice number and the date of the sale from that wholesale distributor to the authorized recipient); and

c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.b. that the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

4. The redistribution of a prescription drug that is not a specified prescription drug as defined in subsection 64F-12.001(2), F.A.C. which was purchased before July 1, 2006 and returned by the purchaser after July 1, 2006, may be redistributed under the following conditions:

a. The redistribution occurs prior to July 1, 2008, and

b. The wholesale distributor discloses in writing to the purchaser and to the recipient, if different from the purchaser, all prior sales and returns of the prescription drug, including the name of the returning person and the date that the prescription drug was returned.

(h) For purposes of Section 499.01212(2)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual prescription drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit.

The department will adopt the industry standards for each type of prescription drug unit when they are established. One pedigree record may be prepared for a group of serialized prescription drugs, provided the only unique characteristic for the pedigree is the serialization codes.

(i) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesale distributor consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., and that wholesale distributor provides a pedigree to its customer consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., the wholesale distributor must

transmit the pedigree information initiated by the manufacturer in the pedigree the wholesale distributor provides to its customer.

(j) A wholesale distributor that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesale distributor prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (i) above.

(k) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.01212(2), F.S., to provide a pedigree paper upon distribution of the manufacturer's prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a prescription drug manufacturer or non-resident prescription drug manufacturer, as applicable, based on its relationship with the manufacturer.

(l) Emergency Distributions. Notwithstanding Section 499.01212(2), F.S. a wholesale distributor may distribute and a purchasing pharmacy, health care clinic establishment or health care practitioner authorized by law to purchase prescription drugs, may accept a prescription drug for which a pedigree that complies with Section 499.01212(2), F.S., is not available, when the prescription drug is required to treat a specific patient with an emergency medical condition as defined by Section 395.002(9)(a), F.S. The prescribing physician or a health care practitioner otherwise licensed to prescribe the drug shall supply a statement, to the supplying wholesale distributor stating that the emergency meets this rule paragraph's requirements. The a supplying wholesale distributor must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug. In addition, the supplying wholesale distributor must submit to the recipient within 14 calendar days of the emergency distribution a written statement, invoices, or other documentation identifying all prior sales or distributions of the specific unit of the prescription drug that is the subject of this distribution.

~~(a)1. The pedigree papers required by Sections 499.0121(6)(d), (e) and (f), F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.~~

~~2. A copy of the pedigree paper must be maintained by each wholesaler preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesaler preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesaler serves as the repository of its customer's pedigree, the wholesaler must specify on the customer's invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.~~

~~(b) If a wholesale distributor uses the statement contained in Section 499.0121(6)(c)1.a.(II), F.S., "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer" the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.~~

~~(c) Beginning July 1, 2006, "Pedigree Paper (Distribution History of Prescription Drugs)," either Form DH 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2129 must be used to comply with the requirement in Section 499.0121(6)(f), F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either "Prescription (legend) Drug Pedigree – Repackager" Form DH 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2135. A wholesaler that further distributes a repackaged prescription drug must include in the pedigree the information related to the repacked drug contained in Form DH 2135 or the electronic record that contains all the elements of Form DH 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.0121(6)(d) or (e), F.S., at the discretion of the wholesaler. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-Rom or smart card or similar devices. Additional information to that~~

~~required by forms DH 2129 and DH 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.~~

~~(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesaler providing the pedigree paper.~~

~~(e) Effective March 1, 2004, a pedigree paper under Section 499.0121(6)(d), F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record on its web site at www.doh.state.fl.us/pharmacy/drugs. A prescription drug wholesaler that receives or prepares a pedigree paper under Section 499.0121(6)(d), F.S., and this chapter that traces the previous distributions of a prescription drug back to a prescription drug wholesaler that is not listed on the department's web site as an authorized distributor of record for the drug's manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesaler is an authorized distributor of record in accordance with the criteria of Section 499.0121(6)(d)5.a., b., or c., F.S.~~

~~(f) Returns.~~

~~1. When a distribution of a prescription drug by a wholesaler to an authorized recipient is the result of a mistake in ordering or shipment, the return of that shipment by the authorized recipient to the wholesaler need not be reflected in the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within seven calendar days after the date of receipt of the original shipment:~~

~~a. The authorized recipient ships the specific unit of the prescription drug back to the wholesaler from which that specific unit was purchased; or~~

~~b. The authorized recipient transmits a documented communication to the wholesaler from which the prescription drug was purchased stating the authorized recipient's intent to return the shipment in accordance with the wholesaler's prescribed written policies and procedures and the wholesaler communicates authorization for return of the product.~~

~~2. Any returns to a wholesaler by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in the pedigree paper trail for any further distributions of the returned drug product to the extent required by Section 499.0121(6)(d), (e) or (f), F.S.~~

~~3. An authorized recipient that returns a shipment to the wholesaler in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product,~~

~~a. That the specific unit (exact unit) being returned was purchased from the receiving wholesaler (including the corresponding sales invoice number and the date of the sale from that wholesaler to the authorized recipient); and~~

~~b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.~~

~~c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.~~

~~(g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.~~

~~(h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesaler consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., (and that wholesaler provides a pedigree to its customer consistent with the standards in sub-subparagraph 64F-12.013(5)(d)1.f., F.A.C., the wholesaler must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesaler provides to its customer.~~

~~(i) A wholesaler that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesaler prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (h) above.~~

~~(j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.0121(6)(f), F.S., to provide a pedigree paper upon distribution of the manufacturer's prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on its relationship with the manufacturer.~~

~~(k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree that complies with Section 499.0121(6)(f), F.S., is not available,~~

~~when the prescription drug is required immediately to treat a specific patient with a life-threatening medical condition or a medical condition that will result in serious bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to the supplying wholesale distributor(s) that the emergency meets this rule paragraph's requirements and the supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.~~

(4) Retailers of veterinary legend drugs or medical oxygen must also maintain a prescription or other order of an authorized practitioner evidencing the authority of the purchaser or recipient to receive the veterinary legend drug or medical oxygen. A veterinary legend drug retailer must have the prescription prior to delivery of the drug to the customer. In the case of a medical oxygen retailer, the prescription or order for medical oxygen must be in writing and in the possession of the retailer within 30 days of delivery of the drug to the patient. An order or prescription for veterinary legend drugs or medical oxygen does not constitute authority for the retailer to sell to the purchaser beyond 12 months from the date of the original sale.

(5) A copy of the Florida Drug and Cosmetic Act, Chapter 499, F.S., and Chapter 64F-12, F.A.C., Regulations for Drugs, Devices and Cosmetics, must be at the permitted establishment.

(6)(a) Records for permittees not physically located within the state may be maintained at a central location outside of the state but must be made available for inspection at a permitted establishment or at the department's address within 2 working days after a request for inspection.

(b) Records for permittees located in the state or persons located in Florida and required to be permitted under Chapter 499, F.S., may be stored by computer or other electronic means at a central location inside or outside of the state, but must be readily available and immediately retrievable, i.e., subject to inspection at the permitted establishment during the inspection.

1. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to Sections 499.001-.081, F.S., in that person's name.

2. If not maintained at a central location, records must be maintained at the permitted location or, if not otherwise permitted, at the address reflected on the product registration.

3. A permitted establishment in Florida that maintains records at a location outside of the state must have a method, such as computerized access, to make records readily available and immediately retrievable. These records must also be made available at the permitted establishment for copying or reproducing within two working days after a request.

4. An establishment permitted at an address outside of the state must make records available for inspection within two working days after a request.

(c) Records for permittees may be copied or reproduced by the department or the Florida Department of Law Enforcement.

(d) If hard copies (originals or true copies) of required records are not maintained at the permitted establishment in Florida, the department or Florida Department of Law Enforcement must be able to review automated records for any and all records required to be maintained under Chapter 499, F.S., without requesting a specific source, recipient, product, date, etc.

(7) Except as provided in Section 499.012(2)(e), F.S., ~~and paragraph (3)(b) of this rule,~~ records of other persons not required to be permitted but subject to regulation under Chapter 499, F.S., must be made available to the department or the Florida Department of Law Enforcement within five business days of the request for inspection, copying, or reproduction.

(8) Records involving drugs, devices, or cosmetics may be maintained by electronic methods, such as computers or imaging devices. Originals or true copies of required records documentation must be maintained by the person involved in the transaction, including brokers and agents. If electronic methods are used to maintain records related to prescription drugs and these methods do not maintain a true copy of the original record, such as the actual image of the original document, then the security system of the permittee must provide protection against tampering with computers or electronic records.

(9) Documentation provided to the department pursuant to an inspection may not be altered or defaced in any manner to obstruct or conceal any required or other information recorded on the document.

(10) All required records must be retained for a period of two years following disposition of the drug, device or cosmetic, or three years after the creation of the records, whichever period is longer; and must be available to the department for such period or as long as records are retained if longer. Records must be retained beyond the retention period if the person has been notified that an investigation or inspection has been initiated by the department and the investigation has not been completed when the mandatory retention period expires.

(11) Manufacturers shall maintain formulas of drugs and cosmetics, including all ingredients, and shall make these available to the department upon request, either during an inspection or by certified mail.

(12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or business. A person permitted under Chapter 499, F.S., that also conducts

other business activities not permitted under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other business activities. For the purpose of this rule, those operational systems required to be kept separate and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A Retail Pharmacy Drug Wholesale Distributor or a Restricted Prescription Drug Distributor-Health Care Entity ~~Wholesaler~~ however, is not required to maintain its stock of prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription drugs which may be dispensed ~~by a retail pharmacy~~.

(13) An establishment permitted to purchase or possess prescription drugs that has no records or has not done any business under the permit that would require such records, shall upon request, provide to the department a written statement to that effect.

(14) The recordkeeping requirements of this ~~sub~~section do not apply to the prescription dispensing records of a pharmacy or to the patient medical records of a licensed practitioner; however, such records may be required to be produced pursuant to a subpoena issued by the department under Section 499.002 ~~499.0053~~, F.S. Notwithstanding any other provision in this section to the contrary, a pharmacy that sells a prescription drug to any person other than a patient or consumer of a given prescription drug, for each sales transaction, must maintain the audit trail records described in subsections (2)(a), (b) (c), (d) above and described in Section 499.0121(6)(a)1. through 5., F.S. whether or not the pharmacy maintains it is not a wholesale distributor of the prescription drug. The records must be maintained in a manner that the records can be inspected by and originals or copies provided to the Department without the record owner or record custodian having to provide or disclose to the Department information that would reveal the name or identity of a patient, or provide the Department with a patient record within the meaning of Section 456.057, F.S.

(15) Charitable Donations of Prescription Drug. A physician or other authorized recipient donating prescription drugs, including prescription drug samples, pursuant to Section 499.012(1)(a)2.e., F.S., must prepare and maintain a donation record that includes at a minimum:

(a) The donor's name, address, telephone number, the practitioner's state license number, and D.E.A. number if a controlled substance is donated;

(b) The manufacturer, brand name, strength, and dosage form of the product; the quantity donated by lot number; and the expiration date of the product;

(c) The date of the donation;

(d) The name, address, and state license number that authorizes the possession of prescription drugs by the charitable organization, if applicable; and

(e) Within 48 hours of receipt, excluding holidays and weekends, the recipient charitable institution must provide a written receipt to the donor acknowledging receipt of the donated prescription drugs.

~~(16) Establishing an ongoing relationship pursuant to Sections 499.0121(6)(d)5.b. and c., F.S. A wholesale distributor that is not listed as an authorized distributor of record on the list submitted to the department by a prescription drug manufacturer may request the department add the wholesale distributor to the department's web site of authorized distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.0121(6)(d), F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.~~

~~(a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.b., F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesaler establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.b., F.S.~~

~~1. To document total annual prescription drug sales of $100 million or more submit either:~~

~~a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR~~

~~b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR~~

~~c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12 month period ending on the last day of the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales, excluding customer returns. and~~

2. For each manufacturer for whom the wholesaler claims authorized distributor of record status, submit both subparagraphs a.and b. to document that the wholesaler annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer's prescription drug products directly from that manufacturer.

a. A computerized listing of all of a manufacturer's prescription drugs purchased by the wholesaler during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled. AND

b.i. A computerized listing of all purchases of a manufacturer's prescription drugs directly from the manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesaler's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer. OR

ii. Copies of the manufacturer's sales invoices of prescription drugs to the wholesaler. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesaler's purchases of a manufacturer's prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

3. Each wholesaler establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group's ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesaler establishment, must submit the names and address of all member wholesaler establishments of the affiliated group. In addition, each wholesaler establishment must either:

a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as the affiliated group upon which the eligibility criteria for the affiliated group was met, or

b. Hold a valid prescription drug wholesaler permit or out-of-state prescription drug wholesaler permit issued under Chapter 499, F.S.

(b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.0121(6)(d)5.c., F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:

a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR

b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR

c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period based on the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales, excluding customer returns.

2. For each manufacturer for whom the wholesaler claims authorized distributor of record status, submit a., b., or c. to document that the wholesaler has a verifiable account number issued by the manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the verifiable account number.

a. If the wholesaler is a member of an affiliated group and all purchases from that manufacturer are made at a central location for the wholesaler, copies of at least 12 invoices dated during the previous 12 months from the date the information is submitted, which invoices document purchases of prescription drugs, at least one unit of which on each invoice was not returned, under that central account number but shipped to the wholesaler's address for whom the authorized distributor of record status is claimed. A statement must be provided that the invoices document purchases of prescription drugs for the wholesaler for whom the authorized distributor of record status is claimed and that the wholesaler did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

b. If the wholesaler is a member of an affiliated group and all purchases from that manufacturer are made at a central location and received at a central location for the wholesaler, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number which is clearly assigned to the wholesaler at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that central location and that the central location or wholesaler for which the drugs were obtained did not return to the manufacturer at least one unit of the prescription drugs on each invoice, and that the central

~~location shipped at least 12 times to the individual wholesaler for whom the authorized distributor of record status is claimed during the 12 months based on the fiscal year or designated timeframe.~~

~~c. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account number that is clearly assigned to the wholesaler at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that wholesaler and that the wholesaler did not return to the manufacturer at least one unit of the prescription drugs on each invoice.~~

Specific Authority 499.003(31), 499.024, 499.025(5), 499.01(6), 499.0121(6), 499.0122(2), 499.012(12), 499.013(3), 499.014(5), 499.03(4), 499.05 FS. Law Implemented 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History–New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06, 12-27-07, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Rebecca Poston, R.Ph.

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Dr. Ana Viamonte Ros

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 23, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 18, 2008

DEPARTMENT OF HEALTH

Division of Family Health Services

RULE NO.:	RULE TITLE:
64F-12.013	Prescription Drugs; Receipt, Storage and Security

PURPOSE AND EFFECT: This rule section is being updated in response to statutory changes, which may include but are not limited to changes made to Chapter 499, Part I, F.S. made by the 2008 Florida Legislature.

SUMMARY: This rule section will clarify authentication of pedigree requirements regarding medical convenience kits, and to revise the term “wholesaler” to “wholesale distributor”.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 499.0121(1), 499.05 FS.

LAW IMPLEMENTED: 499.002, 499.003, 499.004, 499.006, 499.007, 499.012, 499.0121, 499.01212, 499.028(6), 499.05, 499.052 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, R.Ph., Executive Director, Drugs Devices and Cosmetics Program, 4052 Bald Cypress Way, Mail Bin C04, Tallahassee, Florida 32399, (850)245-4292

THE FULL TEXT OF THE PROPOSED RULE IS:

64F-12.013 Prescription Drugs; Receipt, Storage and Security.

(1) Establishments in which prescription drugs are stored, manufactured, repackaged, kept, held, used, sold, stored, offered for sale, or exposed for sale, shall be secured against unauthorized entry or unauthorized access to prescription drugs when establishment personnel are not present.

(a) Establishments permitted under Chapter 499, F.S., that are authorized to take possession of prescription drugs, other than medical oxygen, must be secured by an alarm system which functionally and practically provides a deterrent to unauthorized entry to the establishment or the area where the prescription drugs are held or stored.

(b) Prescription medical oxygen may be stored outside in an area surrounded by a fenced enclosure with a lock which must be secure when authorized persons are not present. Other compressed medical gases must be stored in accordance with paragraph (a).

(2)(a) While not being used to make deliveries, a vehicle of a permittee containing prescription medical oxygen must be parked at the permitted establishment and either locked inside a fenced compound or secured by a vehicle alarm system. A vehicle containing prescription medical oxygen may only be parked at a residence temporarily while the vehicle is making deliveries or while “on call” for emergency deliveries.

(b) When a vehicle used for prescription drug wholesale distributions or for distributions subject to a restricted prescription drug distributor’s permit contains prescription drugs and is not being used to make deliveries, it must be parked inside a building secured by an alarm system.

(c) A residence cannot be used to store any prescription drug which has not been dispensed, unless a natural person residing at that residence is licensed or otherwise authorized to possess prescription drugs.

(3)(a) The storage temperature definitions in the U.S.P. are incorporated by reference herein. If no storage and temperature requirements are set forth by the manufacturer in the labeling or in the U.S.P., prescription drugs other than compressed medical gases must be stored at controlled room temperature. Compressed medical gases, unless otherwise indicated, may be stored in a manner so that they are protected from freezing and are not stored at or near excessive heat or open flame.

(b) All establishments permitted under Chapter 499, F.S., that handle prescription drugs other than medical gases, must, in the absence of electronic monitoring devices, mount two thermometers in the immediate area of the stored prescription drugs. For purposes of this provision, immediate area of the stored prescription drugs is within six (6) feet of the prescription drugs in storage. One thermometer will be mounted in the warmest area of the stored prescription drugs and the other thermometer will be mounted in the coolest immediate area of the stored prescription drugs.

(c) A record must be maintained recording the date; time; thermometer one temperature; thermometer two temperature; and the initials of the person recording the data or reviewing the data if electronically monitored. This record and temperature reading must be recorded at least five (5) days each week with the temperature readings taken between 2:00 p.m. and 4:00 p.m. E.S.T. Alternate times may be approved by the department in writing. This record must be kept on file by the facility for at least two years.

(d) Facility requirements for the storage and handling of prescription drugs.

1. An applicant for an initial prescription drug wholesale distributor ~~wholesaler~~ permit must have a facility that is large enough to store the estimated quantity of prescription drugs the applicant intends to possess under its initial application to comply with the requirements of Section 499.0121(1), F.S. An applicant for renewal of a prescription drug wholesale distributor ~~wholesaler~~ permit must have a facility that is large enough for the ongoing operations of the wholesale distributor establishment based on the prior year's volume of activity with prescription drugs, which may be modified for reasonable fluctuations in inventory management for the current year. These determinations will be based on the type of prescription drugs the applicant possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the facility must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

2. An applicant for an initial prescription drug wholesale distributor ~~wholesaler~~ permit must have a refrigeration capacity and freezer capacity large enough to store the estimated quantity of prescription drugs that might require refrigeration or freezing that the applicant intends to possess under its initial application to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. An applicant for renewal of a prescription drug wholesale distributor ~~wholesaler~~ permit must have a refrigeration capacity and freezer capacity that is large enough for the ongoing operations of the wholesale establishment based on the prior year's volume of activity with prescription drugs that required refrigeration or freezing, which may be modified for reasonable fluctuations in inventory management for the current year, to comply with the requirements of Sections 499.0121(1) and (3), F.S., and this rule. These determinations will be based on the type of prescription drugs the applicant possesses, or intends to possess, considering the size of the containers as well as any other products the applicant possesses or intends to possess that might require refrigeration or freezing. Notwithstanding the contention that an applicant will distribute all prescription drugs the same day received, the refrigeration and freezer capacity must be large enough to accommodate prescription drugs as set forth herein in case the drugs are not distributed the same day received.

(4) Quarantine.

(a) A quarantine section shall be clearly marked and designated separate and apart from any other place where drugs are stored so that products therein shall not be confused with usable products being held for sale. Any prescription drug stored outside the quarantine area is a product held for sale or other distribution.

(b) The requirement of Section 499.0121(5)(b), F.S., that prescription drugs must be quarantined if damage has occurred to the immediate or sealed outer or sealed secondary containers means: a prescription drug must be quarantined if obvious damage, determined by a visual inspection of the exterior of the product's packaging, has occurred to any part of the packaging that is or may be in direct contact with the dosage form of the drug or any additional part of the packaging which is provided to prevent adulteration of the drug in addition to "containing" the product.

(c) A person who handles both prescription drugs and over-the-counter drugs or medical devices may have one quarantine section; however, the storage requirements for prescription drugs must be followed.

(5) Examination of Prescription Drugs; Physical Product and Records.

(a)1. Every person receiving prescription drugs other than the consumer receiving dispensed prescription drugs pursuant to Chapter 465, F.S., has a duty to examine the product to prevent acceptance of prescription drugs that are unfit for distribution or use. The extent of the examination should be predicated on the conditions surrounding the transaction, including but not limited to any previous sales of the product,

i.e., purchase and delivery is not direct from the manufacturer; the conditions of transport; and environmental conditions to which the product may have been subjected.

2. A wholesale distributor ~~wholesaler~~, chain pharmacy warehouse, or person authorized to administer or dispense a prescription drug that physically receives a prescription drug must verify that the prescription drug received matches the prescription drug identified on the corresponding pedigree. The corresponding pedigree document shall contain all of the required information described in Section~~s~~ 499.01212(2)(a) or (b), ~~499.003(31)(a) or (b)~~, F.S. as applicable, including the information required in the forms described in subsection 64F-12.012(3), F.A.C., for those distributions that are not eligible for the use of the direct purchase pedigree by being within the normal distribution chain.

(b) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of misbranded drugs, adulterated drugs or prescription drugs that are otherwise unfit for distribution. If visual examination of the shipping container or other conditions surrounding the transaction suggest possible misbranding or adulteration, the person has a duty to examine further the contents or conditions of sale.

(c) Prescription Drug Wholesale Distributors ~~Wholesalers~~ must employ personnel who can perform product examinations. Once the Prescription Drug Wholesale Distributor ~~Wholesaler~~ has inspected the shipped drugs and elected to accept them, the wholesale distributor ~~wholesalers~~ is responsible for the condition of the drugs. Until that time, the shipper or manufacturer remains responsible for delivering a prescription drug product in acceptable condition, unless responsibilities are modified by contract.

(d) Authentication.

1. A prescription drug wholesale distributor ~~wholesaler~~ may use any, all, or any combination of the following methods to authenticate each transaction on a pedigree paper and must maintain the corresponding documentation regarding the authentication for the method used:

a. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include at a minimum a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesale distributor ~~wholesaler~~ must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesale distributor ~~wholesaler~~, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in sub-subparagraph b., c., or d. below. Each wholesale distributor ~~wholesaler~~ shall establish and adhere to policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically valid standards.

b. Telephone call to the seller. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

c. E-mail communication with the seller. Documentation requirements include a copy of the e-mail that identifies the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

d. Verification of the transaction per a web-based system established by the seller or an independent person that is secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transaction(s). Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the web site and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the (dated) web site page that confirms the sales transaction between the parties, including the date of the transaction and the quantity of prescription drugs involved in the transaction.

e. Receipt of a legible and unaltered copy of a previous transaction's pedigree paper that had been signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesale distributor ~~wholesaler~~ must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in sub-subparagraph b., c., or d. above. Each wholesale distributor ~~wholesaler~~ shall establish and adhere to policies and procedures for the random verification of the authenticity of these copies of pedigrees according to statistically valid standards.

f. Receipt of a pedigree in an electronic form from an automated system that complies with this sub-subparagraph that was successfully opened and decrypted by an automated system that complies with this sub-subparagraph. In order to rely on receipt of an electronic pedigree without employing additional authentication methods as set forth in sub-subparagraphs a.-e.,

(I) The system used to digitally sign and electronically authenticate the electronic pedigree must at a minimum support the following digital signature standards or future revisions governed by the National Institute of Standard and Technology (NIST):

(A) FIPS 140-2 validated cryptographic module which is hereby adopted by reference,

(B) FIPS 186-2 validated digital signature system which is hereby adopted by reference,

(C) FIPS 180-2 validated hash function which is hereby adopted by reference,

(II) The system must employ controls to ensure the security and integrity of the private key so that it cannot be accessed by someone other than the certificate holder. At a minimum, the system must:

(A) Control the activation of the private key with an authentication mechanism,

(B) Employ a ten-minute inactivity time period after which the certificate holder must re-authenticate to access the private key,

(C) When the signing module is deactivated, clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key,

(III) The system must communicate with the Certification Authority directory, either each time authentication and validation steps in sub-subparagraph (IX) below occur or at least on a daily basis to download information to perform the authentication and validation which will occur on that day.

(IV) The system must have a time system that is within five minutes of the official NIST time source and date and time stamp any and all digital signatures.

(V) The system must archive digitally signed files unaltered, including the original hashes and reference to the public keys, in a manner that facilitates retrieval of the record consistent with the recordkeeping requirements.

(VI) The system must prevent issuance of an outgoing pedigree paper if the total quantity of prescription drugs distributed in all pedigrees exceeds the quantity of prescription drugs received in the corresponding incoming electronic pedigree.

(VII) The system must maintain a history file of any outgoing electronic pedigree that is subsequently voided or altered and notify the recipient that the pedigree sent to it was voided or altered.

(VIII) The system must maintain a history file of any incoming notification received pursuant to sub-sub-subparagraph (VII) above that a pedigree was voided or altered and prevent the issuance of an outgoing pedigree using a pedigree that was voided or altered.

(IX) The system must verify or perform the following:

(A) Each transaction on the electronic pedigree must be digitally signed using certificates issued through a public key infrastructure system authorized by the department.

(B) The electronic pedigree must contain each prior transaction digitally signed and unaltered, including the original hash and reference to the public key, with the new transaction information appended to the new document and the entire resulting pedigree digitally signed, including the resulting hash and reference to the public key.

(C) The system must check the certificate expiration date of each signed transaction and compare it against the date and time that the transaction was signed to determine that the certificate has not or had not expired at the time the record was signed.

(D) The system must check the digital signature for each signed transaction against the Certificate Authority's directory and the Certificate Revocation List and verify whether the certificate holder is or was authorized to sign electronic pedigrees at the time the transaction was signed.

(E) The system must decrypt each digital signature for each signed transaction in the pedigree using each sender's public key and compare it against the message digest to determine that the record has not been altered since it was originally signed.

(F) The system must require that all authentication and validation steps in the preceding paragraphs are carried out prior to allowing the acceptance of the transaction. The system should not allow the further processing of any transaction that has failed to pass any authentication or validation step.

(X)(A) The manufacturer must initiate the pedigree; or, until such time as the manufacturer initiates a pedigree to the wholesale distributor ~~wholesaler~~, the wholesale distributor ~~wholesaler~~ that purchased the prescription drug from the manufacturer must imbed a copy of the sales invoice or the manufacturer's EDI transmission or Advance Ship Notice (ASN) that contains all required data elements for a complete audit trail as set forth in Rule 64F-12.012, F.A.C., related to that wholesale distributor's ~~wholesaler's~~ acquisition of the prescription drug from the manufacturer. Price information related to the transaction may be redacted from the imbedded copy of the sales invoice, the EDI transmission, or the ASN.

(B) If a pedigree complies with all provisions within sub-subparagraph f. except for sub-sub-sub-subparagraph (X)(A) above, then a prescription drug wholesale distributor ~~wholesaler~~ must use another method authorized by this rule to authenticate the distribution from the manufacturer to the first wholesale distributor ~~wholesaler~~. Subsequent distributions may be authenticated in accordance with sub-subparagraph f.

2. If a pedigree cannot be authenticated because of a clerical error, the pedigree must be corrected by the sender.

3. If a pedigree cannot be authenticated and the reason is other than a clerical error, or the reason cannot be satisfactorily ascertained based on preliminary investigation, the prescription

drug for which the pedigree cannot be authenticated must be quarantined and the department notified within 3 business days.

4. A purchasing wholesale distributor ~~wholesaler~~ may use a written contract between the purchasing wholesale distributor ~~wholesaler~~ and its wholesale supplier, which is a primary wholesale distributor ~~wholesaler~~ as defined in Section 499.003 (36), ~~499.012(1)(d),~~ F.S., that requires that all prescription drugs distributed to the purchasing wholesale distributor ~~wholesaler~~ by the wholesale supplier must be purchased by the wholesale supplier from the manufacturer. If this method is used to authenticate a pedigree, the purchasing wholesale distributor ~~wholesaler~~ shall establish and adhere to policies and procedures for the random verification of the authenticity of the pedigrees that disclose the wholesale supplier ~~wholesaler~~ purchased the prescription drug from the manufacturer according to statistically valid standards.

5. The following persons in Florida that are authorized to purchase or possess prescription drugs are not required to authenticate a pedigree paper received from a person authorized by law to distribute prescription drugs to that person:

a. A licensed pharmacy, unless it is also permitted as a retail pharmacy drug wholesale distributor ~~wholesaler~~ and will engage in the wholesale distribution of that drug, or unless it is a member of an affiliated group and will distribute a prescription drug purchased or received directly from a prescription drug wholesale distributor ~~wholesaler~~ that is not also a member of its affiliated group to another member of its affiliated group;

b. A medical practitioner; ~~or~~

c. A restricted prescription drug distributor – health care entity; ~~.~~or

d. A health care clinic establishment.

6. In order to authenticate pedigrees, a manufacturer of a prescription drug that is sold or distributed in Florida must make available upon request information relevant to authenticating a pedigree for that drug regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

7. Any wholesale distributor ~~wholesaler~~ or repackager required under Chapter 499, F.S., to receive a pedigree paper must authenticate the pedigree pursuant to Section 499.0121(4), F.S., notwithstanding the absence of a pedigree paper or authentication by persons in the distribution chain not subject to the requirements of Chapter 499, F.S.

8. Convenience Kits; A wholesale distributor is not required to open a sealed medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.

9. All wholesale distributors of prescription drugs, unless exempted in this rule section from the requirement to authenticate a pedigree, are required to authenticate the pedigree upon receipt of the prescription drug. The authentication requirement includes but its not limited to authentication of pedigree transactions involving prescription drugs included within a sealed medical convenience kit.

(6) Any establishment that is permitted as a prescription drug wholesale distributor ~~wholesaler~~ or repackager must notify the department in writing within three working days of discovery of a significant loss or theft of prescription drugs. Whether a loss or theft is significant is to be based on the prescription drug wholesale distributor's ~~wholesaler's~~ written policies and procedures that may take into account the actual quantity in relation to the type or size of the business; any pattern of losses or thefts; and local trends or other indicators of the diversion potential. Notification to the Drugs, Devices and Cosmetic Program may be made by facsimile to (850)413-6982 and must include at a minimum, identification of the permitted establishment reporting the loss or theft; a complete identification of the prescription drug(s) involved, including but not limited to the name of the manufacturer or distributor reflected on the label of the products, the dosage form, strength, container size, the quantity of each, the lot numbers if known; a brief description of the circumstances surrounding the theft or loss; and a contact person's name and telephone number to provide additional information.

(7) Due Diligence Inspection. With respect to the inspection required under Section 499.0121(13)~~(12)~~(e), F.S., a prescription drug wholesale distributor ~~wholesaler~~ may rely on a due diligence inspection performed by a person that is independent of both wholesale distributors ~~wholesalers~~ for purposes of the requirement in Section 499.0121(13)~~(12)~~(e), F.S.

Specific Authority 499.0121(1), 499.05 FS. Law Implemented 499.004, 499.006, 499.007, 499.0121, 499.028(6), 499.052 FS. History–New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-86, 7-1-96, Formerly 10D-45.0535, Amended 1-26-99, 4-17-01, 1-1-04, 1-19-06, 11-18-07, _____.

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NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Dr. Ana Viamonte Ros

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: December 23, 2008

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