

**REPORT ON EXAMINATION**  
**OF**  
**FCCI INSURANCE COMPANY**  
**SARASOTA, FLORIDA**

**AS OF**  
**DECEMBER 31, 2010**

**BY THE**  
**OFFICE OF INSURANCE REGULATION**

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**TALLAHASSEE, FLORIDA**

**October 27, 2011**

Kevin M. McCarty  
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Office of Insurance Regulation  
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Dear Sirs and Madam:

Pursuant to your instructions, in compliance with Section 624.316, Florida Statutes, and Rule 690-138.05, Florida Administrative Code, and in accordance with the practices and procedures promulgated by the National Association of Insurance Commissioners (NAIC), we have conducted an examination as of December 31, 2010, of the financial condition and corporate affairs of:

**FCCI INSURANCE COMPANY  
6300 UNIVERSITY PARKWAY  
SARASOTA, FLORIDA 34240**

Hereinafter referred to as, the "Company". Such report of examination is herewith respectfully submitted.

## **SCOPE OF EXAMINATION**

This examination covered the period of January 1, 2006, through December 31, 2010. The Company was last examined by representatives of the Florida Office of Insurance Regulation (Office) as of December 31, 2005. This examination commenced with planning at the Office from July 18, 2011 to July 22, 2011. The fieldwork commenced on July 25, 2011, and concluded as of October 27, 2011.

This financial examination was a statutory association financial examination conducted in accordance with the Financial Condition Examiners Handbook, Accounting Practices and Procedures Manual and annual statement instructions promulgated by the NAIC as adopted by Rules 69O-137.001(4) and 69O-138.001, Florida Administrative Code, with due regard to the statutory requirements of the insurance laws and rules of the State of Florida.

The Financial Condition Examiners Handbook requires that the examination be planned and performed to evaluate the financial condition and identify prospective risks of the Company by obtaining information about the Company including corporate governance, identifying and assessing inherent risks within the Company, and evaluating system controls and procedures used to mitigate those risks. An examination also includes assessing the principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation and management's compliance with Statutory Accounting Principles and annual statement instructions when applicable to domestic state regulations.

All accounts and activities of the Company were considered in accordance with the risk-focused examination process.

This report of examination is confined to significant adverse findings, a material change in the financial statements or other information of regulatory significance or requiring regulatory action. The report comments on matters that involved departures from laws, regulations or rules, or which were deemed to require special explanation or description.

## **SUMMARY OF SIGNIFICANT FINDINGS**

### **Current Exam Findings**

There were no material findings or exceptions noted during the examination as of December 31, 2010.

### **Prior Exam Findings**

The following is a brief summary of items of interest, findings and corrective action contained in the Office's prior examination report as of December 31, 2005, along with resulting action taken by the Company in connection therewith.

#### **General - Loans**

The Company loaned \$35 million in December, 2003 to FCCI Services, Inc. to pay off the debt of the home office owed to Sun Trust Bank. The Company had no intercompany notes between the parties. The Company did not obtain approval from the Office for these loans and Company did not maintain written loan documents. **Resolution: The Company adopted the recommendation for future compliance with Rule 690-143.047(4)(a).**

### **Holding Company Registration Statement**

The Company did not have required disclosures in their holding company registration statements related to: (1) pledged money for reinsurance treaties; (2) pledged money for a line of credit; and (3) a statement that loans to FCCI Services, Inc. were not done timely.

**Resolution: The Company adopted the Office's recommendation and will continue to disclose such filings in the future.**

### **Custodial Agreement**

The Company maintained a custodial agreement with The Northern Trust Bank which did not contain one of the required clauses in accordance with Rule 69O-143.042(2)(o), Florida Administrative Code, which requires a clause that states the agreement must be terminable by the Insurance company on not more than a 30 day notice. **Resolution: The Company corrected the agreement to comply with Rule 69O-143.042(2)(o), Florida Administrative Code.**

## **HISTORY**

### **General**

The Company was organized in Florida on April 1, 1959 as Florida Construction Commerce & Industry Self Insurers Fund and converted in 1994 to FCCI Mutual Insurance Company. FCCI Mutual Insurance Company was converted in 1998 to FCCI Insurance Company, a stock company, which was wholly-owned by FCCI Group, Inc.

The Company was authorized to transact the following insurance coverage in Florida on December 31, 2010:

Fire	Allied lines
Farmowners multi peril	Inland marine
Commercial multi peril	Workers' compensation
Earthquake	Commercial auto physical damage
Other liability – (including Product liability)	Commercial automobile liability
Private passenger auto physical damage	Surety
Fidelity	Burglary and theft
Glass	
Boiler and machinery	

The Articles of Incorporation and the Bylaws were not amended during the period covered by this examination.

### **Dividends to Stockholders**

No dividends were declared or paid during the period covered by this examination.

### **Capital Stock and Capital Contributions**

FCCI Insurance Company wholly owns FCCI Insurance Group, Inc., which wholly owns National Trust Insurance Company; Monroe Guaranty Insurance Company; FCCI Commercial Insurance Company; FCCI Services, Inc. (FSI); FCCI Advantage Insurance Company and Brierfield Insurance Company.

As of December 31, 2010, the Company's capitalization was as follows:

Number of authorized class A common capital shares	10,000,000
Number of shares class A issued and outstanding	5,000,000
Number of authorized class B common capital shares	500,000,000
Number of class B common capital shares issued and outstanding	0
Number of preferred stock authorized	10,000,000
Number of preferred stock issued and outstanding	0
Total common capital stock issued	\$5,000,000
Par value per share	\$1.00



The outstanding shares of common stock of the Company are owned by FCCI Group, Inc., an insurance holding company domiciled in the State of Florida.

### **Surplus Debentures**

The Company did not issue any surplus debentures.

### **Acquisitions, Mergers, Disposals, Dissolutions, and Purchase or Sales Through Reinsurance**

There were no acquisitions, mergers, disposals, dissolutions, and purchases or sales through reinsurance during this examination.

## **CORPORATE RECORDS**

The recorded minutes of the shareholder, Board of Directors (Board), and certain internal committees were reviewed for the period under examination. The recorded minutes of the Board adequately documented its meetings and approval of Company transactions and events, including the authorization of investments as required by Section 625.304, Florida Statutes.

### **Conflict of Interest**

The Company adopted a policy statement requiring annual disclosure of conflicts of interest in accordance with the NAIC Financial Condition Examiners Handbook adopted by Rule 69O-138.001, Florida Administrative Code.

## MANAGEMENT AND CONTROL

### Management

The annual shareholder meeting for the election of directors was held in accordance with Section 628.231, Florida Statutes. Directors serving as of December 31, 2010, were:

#### Directors

<b>Name and Location</b>	<b>Principal Occupation</b>
Charles Robert Baumann Sarasota, Florida	Director / CPA
Robert Weld Benjamin Sarasota, Florida	Vice President / Attorney
Timothy Joseph Clarke Sarasota, Florida	President / Marketing Consultant
Robert Winthrop Flanders Sarasota, Florida	President / Business Owner
Marvin Stephen Haber Sarasota, Florida	Retired
Gordon William Jacobs Sarasota, Florida	CEO, FCCI Mutual Insurance Holding Co.
John Thomas Stafford Sarasota, Florida	Vice Chairman / Director
Roy Allan Yahraus Sarasota, Florida	Sales Manager

In accordance with the Company's bylaws, the Board appointed the following senior officers:

#### Senior Officers

<b>Name</b>	<b>Title</b>
Gordon William Jacobs	President & CEO
Debra Horner Douglas	Executive Vice President & Secretary
Craig Allan Johnson	Executive Vice President, CFO & Treasurer
Rupert Lee Willis	Executive Vice President & Chief Regional Officer
Joseph Anthony Keene	Executive Vice President
Christopher Samir Shoucair	Senior Vice President, Controller & Assistant Treasurer

The Company's Board appointed several internal committees. Following were the principal internal board committees and their members as of December 31, 2010:

<b>Executive Committee</b>	<b>Audit Committee</b>	<b>Investment Committee</b>
John Stafford <sup>1</sup> G.W. Jacobs	Charles Baumann <sup>1</sup> Robert Flanders Timothy Clarke Robert Benjamin	Marvin Haber <sup>1</sup> Charles Baumann Timothy Clarke Robert Benjamin

<sup>1</sup> Chairman

## **SUBSEQUENT EVENTS**

There have been changes in the management of the Company subsequent to the examination date. Effective in May 2011: Gordon "G.W." Jacobs, President and Chief Executive Officer retired. Craig Johnson was promoted to President and Chief Executive Officer, Chris Shoucair was promoted to Chief Financial Officer and Treasurer, and Michelle Jalbert was promoted to Controller and Assistant Treasurer.

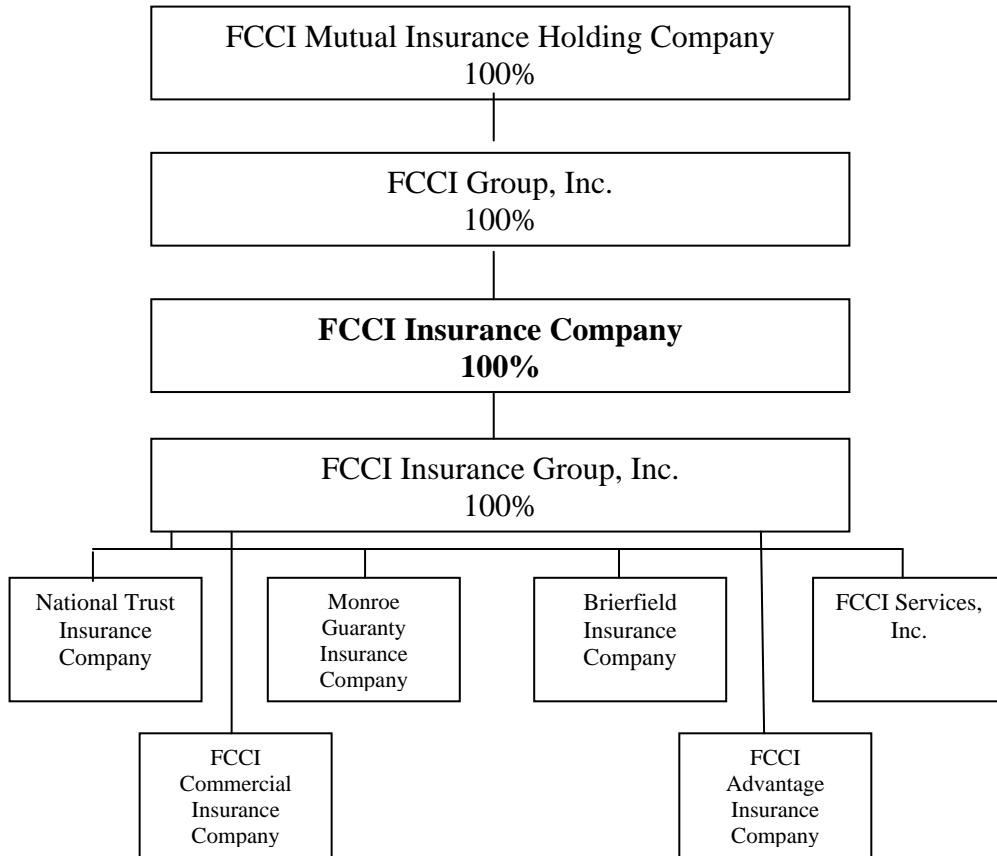
## **Affiliated Companies**

The Company was a member of an insurance holding company system as defined by Rule 69O-143.045(3), Florida Administrative Code. The latest holding company registration statement was filed with the State of Florida on February 28, 2011, as required by Section 628.801, Florida Statutes, and Rule 69O-143.046, Florida Administrative Code.

An organizational chart as of December 31, 2010, reflecting the holding company system, is shown below. Schedule Y of the Company's 2010 annual statement provided a list of all related companies of the holding company group.

# FCCI Insurance Company Organizational Chart

DECEMBER 31, 2010



The following agreements were in effect between the Company and its affiliates:

### **Tax Allocation Agreement**

The Company, along with its affiliates, filed a consolidated federal income tax return. On December 31, 2010, the method of allocation was the “separate-entity” basis described in Internal Revenue Code Section 1552(a)(2) and Treasury Regulation 1552-1(a)(2) which was the percentage of tax each member would bear compared to the total tax of all members, if computed on separate returns.

### **Management Services Agreement**

The Company, along with its parents and affiliates, had a management services agreement with FSI, an affiliate, which provided insurance and general management services including, but not limited to: underwriting, premium formulation, collection services, loss control, claims management, portfolio investment management, actuarial services, accounting services, internal auditing, treasury and banking services, legal services, regulatory affairs, internal operations, personnel, information systems, marketing, facilities management, tax services, reinsurance services, corporate governance, and other services related to the effective management of the Company's business.

### **Reinsurance Agreements**

The Company had 100% quota share assumption reinsurance and loss portfolio transfer agreements with each of its insurance company affiliates.

## **FIDELITY BOND AND OTHER INSURANCE**

The Company's ultimate parent, FCCI Mutual Insurance Holding Company, maintained fidelity bond coverage, which included the Company, up to \$5,000,000 with a deductible of \$50,000, which met the suggested minimum as recommended by the NAIC.

The Company also was a named insured on a commercial property and general liability policy, workers' compensation and employer's liability policy, commercial umbrella liability policy, and business auto policy.

## **PENSION, STOCK OWNERSHIP AND INSURANCE PLANS**

Pension, stock ownership, and insurance plans did not apply to the Company, as it did not have any employees. FCCI Services, Inc. employed all the personnel and through an allocation agreement charged each of the subsidiary companies.

## **TERRITORY AND PLAN OF OPERATIONS**

The Company was authorized to transact insurance in the following states:

Alabama	Illinois	Michigan	Oklahoma
Arizona	Indiana	Mississippi	Pennsylvania
Colorado	Iowa	Missouri	South Carolina
Connecticut	Kansas	Nebraska	Tennessee
Florida	Kentucky	North Carolina	Virginia
Georgia	Maryland	Ohio	

### **Treatment of Policyholders**

The Company established procedures for handling written complaints in accordance with Section 626.9541(1) (j), Florida Statutes. The Company maintained a claims procedure manual that

included detailed procedures for handling each type of claim in accordance with Section 626.9541(1) (i) 3a, Florida Statutes.

## **COMPANY GROWTH**

The Company's earned premiums have decreased over the examination period mainly due to reductions in exposure as a result of overall market conditions and decreases in premium rates as a result of a state mandated rate reduction of 4.2% on Florida workers' compensation business. While workers' compensation premium has declined, policy counts have increased. This was consistent with the market trend as payrolls have declined. The increase in net underwriting gain was primarily due to reductions in loss adjustment expenses incurred, which influenced the increase in net income from 2009 to 2010. The increase in total assets was primarily attributable to the increase in common stock holdings. The net increase in total liabilities was primarily attributable to the decrease in loss and loss adjustment expense reserves and the increase in borrowed money. Surplus as regards policyholders increased nearly 23% over the examination period.

### **Profitability of Company**

The following table shows the profitability trend (in dollars) of the Company for the period of examination, as reported in the filed annual statements.

	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Premiums Earned	\$430,129,033	\$439,249,519	\$476,555,832	\$505,054,173	\$520,847,195
Net Underwriting Gain/(Loss)	(\$4,166,514)	(\$8,280,525)	(\$17,823,167)	\$35,209	\$12,692,671
Net Income	\$39,750,798	\$34,565,755	\$3,349,542	\$28,099,547	\$30,203,713
Total Assets	\$1,526,885,520	\$1,460,733,635	\$1,399,983,650	\$1,407,347,101	\$1,342,308,850
Total Liabilities	\$1,047,766,120	\$1,033,344,124	\$1,023,189,556	\$986,788,834	\$952,166,499
Surplus As Regards Policyholders	\$479,119,400	\$427,389,511	\$376,794,094	\$420,558,267	\$390,142,351

## **LOSS EXPERIENCE**

Incurring losses have decreased over the examination period due to favorable reserve development in the workers' compensation, auto liability, auto physical damage, and commercial multi-peril lines of business. The favorable development was a result of better than expected emerging trends in 2010. This trending resulted in actuarial reductions in reserve estimates on prior accident years.

## **REINSURANCE**

The reinsurance agreements reviewed complied with NAIC standards with respect to the standard insolvency clause, arbitration clause, transfer of risk, reporting and settlement information deadlines.

### **Assumed**

The Company provided reinsurance to five indirectly owned subsidiaries, Monroe Guaranty Insurance Company, National Trust Insurance Company, FCCI Commercial Insurance Company, FCCI Advantage Insurance Company, and Brierfield Insurance Company, under various quota share and loss portfolio transfer reinsurance contracts. The Company reinsured 100% of the exposures in excess of the subsidiaries' retention. The quota share reinsurance contracts included a provision for assumed commission equal to 100% of the subsidiaries' operating expenses incurred. The Company assumed business from mandatory pools in Alabama, Georgia, Illinois, Indiana, Kentucky, Michigan, Mississippi, North Carolina, Ohio, South Carolina and Tennessee.



**Ceded**

The Company ceded risk on an excess of loss and quota share basis to various authorized and unauthorized reinsurers as listed on Schedule F, Part 3 of the annual statement. The three top authorized reinsurers and their respective percentage of total assumed premiums were: General Reinsurance Corporation (17%), Munich Reinsurance America, Inc. (31%), and Swiss Reinsurance America Corporation (34%). The top three unauthorized reinsurers and their respective percentage of the total assumed premium by unauthorized reinsurer were: Axis Specialty Limited (15%), Partner Reinsurance Corporation Limited (17%), and Validus Reinsurance Limited (18%).

The Reinsurance contracts were reviewed by the Company's appointed actuary and were utilized in determining the ultimate loss opinion.

**ACCOUNTS AND RECORDS**

The Company maintained its principal operational offices in Sarasota, Florida.

An independent CPA audited the Company's statutory basis financial statements annually for the years 2006, 2007, 2008, 2009, and 2010 in accordance with Section 624.424(8), Florida Statutes. Supporting work papers were prepared by the CPA as required by Rule 69O-137.002, Florida Administrative Code.

The Company's accounting records were maintained on a computerized system. The Company's balance sheet accounts were verified with the line items of the annual statement submitted to the Office.

The Company and non-affiliates had the following agreements:

### **Custodial Agreement**

The Company had a custodial agreement with Northern Trust Company dated March 13, 2006. It was amended September 7, 2006 and January 1, 2009. The agreement was in compliance with Rule 69O-143.042, Florida Administrative Code.

### **Independent Auditor Agreement**

The Company contracted with an external independent CPA firm to perform the annual audit of its financial statements as required by Rule 69O-137.002 (7) (c), Florida Administrative Code.

## **INFORMATION TECHNOLOGY REPORT**

RSM McGladrey performed an evaluation of the information technology and computer systems of the Company. Results of the evaluation were noted in the Information Technology Report provided to the Company.

## STATUTORY DEPOSITS

The following securities were deposited with the State of Florida as required by Section 624.411, Florida Statutes and with various state officials as required or permitted by law:

<u>STATE</u>	<u>Description</u>	<u>Par Value</u>	<u>Market Value</u>
FL	Freddie Mac, 5.125%, Nov. 2017	\$ 2,500,000	\$ 2,846,775
<b>Total Florida Deposits</b>		\$ 2,500,000	\$ 2,846,775
AZ	First American Treasury Obligation Y	\$ 120,000	\$ 120,000
GA	US Treasury Note, 4.75%, May 2014	100,000	111,727
GA	Wells Fargo Adv TR PL, MM-INS	27,457	27,457
NC	First American Treasury Oblig. Fund	575,000	575,009
OH	US Treasury Note, 4.0%, Nov. 2012	250,000	266,193
OK	US Treasury Note, 4.75%, May 2014	325,000	363,113
VA	US Treasury Note, 4.5%, Feb. 2016	225,000	251,984
USDL	US Treasury Note, 4.75%, May 2014	1,100,000	1,228,997
<b>TOTAL OTHER DEPOSITS</b>		\$ 2,722,457	\$ 2,944,480
<b>TOTAL SPECIAL DEPOSITS</b>		<u>\$ 5,222,457</u>	<u>\$ 5,791,255</u>

## FINANCIAL STATEMENTS PER EXAMINATION

The following pages contain financial statements showing the Company's financial position as of December 31, 2010, and the results of its operations for the year then ended as determined by this examination. Adjustments made as a result of the examination are noted in the section of this report captioned, "Comparative Analysis of Changes in Surplus."

**FCCI INSURANCE COMPANY**

**Assets**

**DECEMBER 31, 2010**

	<b>Per Company</b>	<b>Examination Adjustments</b>	<b>Per Examination</b>
Bonds	\$1,026,636,132		\$1,026,636,132
Stocks:			
Common	240,901,146		240,901,146
Real Estate:			
Properties occupied by Company	37,342,977		37,342,977
Cash and Short-Term Investments	18,724,683		18,724,683
Other invested assets	1,176,389		1,176,389
Receivable for securities	103		103
Investment income due & accrued	11,612,489		11,612,489
Agents' Balances:			
Uncollected premium	8,769,760		8,769,760
Deferred premium	145,407,990		145,407,990
Accrued retrospective premiums	1,546,883		1,546,883
Reinsurance			
Reinsurance recoverable	1,124,005		1,124,005
Funds held with reinsurance companies	48,153		48,153
Net deferred tax asset	32,840,736		32,840,736
Receivable from parents, subsidiaries and affiliates	474,987		474,987
Aggregate write-in for other than invested assets	279,087		279,087
	<hr/>		<hr/>
Totals	<u>\$1,526,885,520</u>	<u>\$0</u>	<u>\$1,526,885,520</u>

**FCCI INSURANCE COMPANY**  
**Liabilities, Surplus and Other Funds**

**DECEMBER 31, 2010**

	Per Company	Examination Adjustments	Per Examination
Losses	\$531,775,630		\$531,775,630
Reinsurance payable	1,118,443		1,118,443
Loss adjustment expenses	146,138,981		146,138,981
Commissions payable, contingent commissions and other similar charges	6,458,016		6,458,016
Other expenses	19,239,809		19,239,809
Taxes, licenses and fees	3,332,370		3,332,370
Current federal and foreign income taxes	2,360,721		2,360,721
Borrowed money	100,040,339		100,040,339
Unearned premium	210,100,222		210,100,222
Dividends declared and unpaid: policyholders	2,731,198		2,731,198
Advance premium	1,873,717		1,873,717
Ceded reinsurance premiums payable	3,478,882		3,478,882
Amounts withheld	1,293,469		1,293,469
Remittances and items not allocated	784,409		784,409
Provision for reinsurance	160,736		160,736
Payable to parent, subsidiaries and affiliates	12,398,257		12,398,257
Aggregate write-ins for liabilities	4,480,921		4,480,921
Total Liabilities	\$1,047,766,120	\$0	\$1,047,766,120
Aggregate write-ins for special surplus funds	\$10,096,997		\$10,096,997
Common capital stock	5,000,000		5,000,000
Unassigned funds (surplus)	464,022,403		464,022,403
Surplus as regards policyholders	\$479,119,400	\$0	\$479,119,400
Total liabilities, surplus and other funds	\$1,526,885,520	\$0	\$1,526,885,520

**FCCI Insurance Company  
Statement of Income**

**DECEMBER 31, 2010**

**Underwriting Income**

Premiums earned		\$430,129,033
	<b>Deductions:</b>	
Losses incurred		\$235,977,269
Loss expenses incurred		47,390,539
Other underwriting expenses incurred		150,927,739
Aggregate write-ins for underwriting deductions		0
Total underwriting deductions		\$434,295,547
Net underwriting gain or (loss)		(\$4,166,514)

**Investment Income**

Net investment income earned		\$44,813,834
Net realized capital gains or (losses)		8,369,275
Net investment gain or (loss)		\$53,183,109

**Other Income**

Net gain or (loss) from agents' or premium balances charged off		(\$1,541,205)
Finance and service charges not included in premiums		743,776
Aggregate write-ins for miscellaneous income		(470,499)
Total other income		(\$1,267,928)
Net income before dividends to policyholders and before federal & foreign income taxes		\$47,748,667
Dividends to policyholders		4,340,919
Net Income, after dividends to policyholders, but before federal & foreign income taxes		\$43,407,748
Federal & foreign income taxes		3,656,950
Net Income		\$39,750,798

**Capital and Surplus Account**

Surplus as regards policyholders, December 31 prior year		\$427,389,511
Net Income		\$39,750,798
Change in net unrealized capital gains or (losses)		7,428,453
Change in net deferred income tax		(6,422,275)
Change in non-admitted assets		10,934,072
Change in provision for reinsurance		38,841
Change in excess statutory over statement reserves		0
Surplus adjustments: Paid in		0
Aggregate write-ins for gains and losses in surplus		0
Examination Adjustment		0
Change in surplus as regards policyholders for the year		\$51,729,889
Surplus as regards policyholders, December 31 current year		\$479,119,400

A comparative analysis of changes in surplus is shown below.

**FCCI INSURANCE COMPANY**  
**Comparative Analysis of Changes in Surplus**

**DECEMBER 31, 2010**

The following is a reconciliation of Surplus as regards policyholders between that reported by the Company and as determined by the examination.

Surplus as Regards Policyholders December 31, 2010, per Annual Statement	\$479,119,400
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	<u>PER COMPANY</u>	<u>PER EXAM</u>	<u>INCREASE (DECREASE) IN SURPLUS</u>
ASSETS:			
No Adjustment			
LIABILITIES:			
No Adjustment			
Net Change in Surplus:			<u>0</u>
Surplus as Regards Policyholders December 31, 2010, Per Examination			<u><u>\$479,119,400</u></u>

## COMMENTS ON FINANCIAL STATEMENTS

### Liabilities

**Losses and Loss Adjustment Expenses** \$677,914,611

An outside actuarial firm appointed by the Board of Directors rendered an opinion that the amounts carried in the balance sheet as of December 31, 2010, made a reasonable provision for all unpaid loss and loss expense obligations of the Company under the terms of its policies and agreements.

The Office engaged an independent actuarial firm, RSM McGladrey, Inc., to review the loss and loss expense obligations carried in the Company's balance sheet as of December 31, 2010. They were in concurrence with this opinion.

### Capital and Surplus

The amount reported by the Company of \$479,119,400 exceeded the minimum of \$89,464,661 required by Section 624.408, Florida Statutes.



## CONCLUSION

The insurance examination practices and procedures as promulgated by the NAIC have been followed in ascertaining the financial condition of **FCCI Insurance Company** as of December 31, 2010, consistent with the insurance laws of the State of Florida.

Per examination findings, the Company's Surplus as regards policyholders was \$479,119,400, which exceeded the minimum of \$89,464,661 required by Section 624.408, Florida Statutes.

In addition to the undersigned, John J. D'Amato, CPA, Examiner-In-Charge; Michael C. Dubin, FCAS MAAA, Consulting Actuary; Jared Rubinstein, Participating Examiner; Amber Webster, Participating Examiner; Philip E. McMurray, CISA IT Manager; and Margaret C. Spencer, CFE all of RSM McGladrey; and Kyra Brown, APIR, Financial Specialist; Syntia King, APIR, Financial Examiner/Analyst II and Kethessa Carpenter, CPA Financial Examiner/Analyst Supervisor of the Office participated in the examination.

Respectfully submitted,

---

Mary James, CFE, CPM  
Chief Examiner  
Florida Office of Insurance Regulation