

Member	City	State
Valley Bank of Ronan	Ronan	Montana.
Citizens Bank	Corvallis	Oregon.
U-Lane-O Credit Union	Eugene	Oregon.
Oregon Pacific Banking Company	Florence	Oregon.
Southern Oregon Federal Credit Union	Grants Pass	Oregon.
Pacific State Bank	Reedsport	Oregon.
St. Helens Community Federal Credit Union	St. Helens	Oregon.
State Bank of Southern Utah	Cedar City	Utah.
Central Bank	Provo	Utah.
Far West Bank	Provo	Utah.
Liberty Bank	Salt Lake City	Utah.
First Mutual Bank	Bellevue	Washington.
Frontier Bank	Everett	Washington.
City Bank	Lynnwood	Washington.
Redmond National Bank	Redmond	Washington.
Washington School Employees Credit Union	Seattle	Washington.
American West Bank	Spokane	Washington.
Numerica Credit Union	Spokane	Washington.
Washington Trust Bank	Spokane	Washington.
Columbia State Bank	Tacoma	Washington.
Harborstone Credit Union	Tacoma	Washington.
Westside Community Bank	University Place	Washington.
Baker Boyer National Bank	Walla Walla	Washington.
Mid State Bank	Waterville	Washington.
First National Bank of Buffalo	Buffalo	Wyoming.
Wyoming Bank and Trust	Cheyenne	Wyoming.
The Jackson State Bank	Jackson	Wyoming.
First Interstate Bank	Sheridan	Wyoming.

II. Public Comments

To encourage the submission of public comments on the community support performance of Bank members, on or before January 28, 2002, each Bank will notify its Advisory Council and nonprofit housing developers, community groups, and other interested parties in its district of the members selected for community support review in the 2000–01 eighth quarter review cycle. 12 CFR 944.2(b)(2)(ii). In reviewing a member for community support compliance, the Finance Board will consider any public comments it has received concerning the member. 12 CFR 944.2(d). To ensure consideration by the Finance Board, comments concerning the community support performance of members selected for the 2000–01 eighth quarter review cycle must be delivered to the Finance Board on or before the February 28, 2002 deadline for submission of Community Support Statements.

By the Federal Housing Finance Board.

Dated: December 21, 2001.

Arnold Intrater,

Acting General Counsel.

[FR Doc. 02-153 Filed 1-10-02; 8:45 am]

BILLING CODE 6725-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 25, 2002.

A. Federal Reserve Bank of Kansas

City (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. *John K. Kingsbury and Myra A. Kingsbury*, Ponca, Nebraska; and Lovice M. Sprugel, Liberty, Missouri, trustee of Lovice M. Sprugel Trust and John E. Sprugel, Liberty, Missouri, trustee of John E. Sprugel Trust; to acquire voting shares of Kingsbury BDC Financial Services, Inc., Ponca, Nebraska, and thereby indirectly acquire voting shares

of The Bank of Dixon County, Ponca, Nebraska.

Board of Governors of the Federal Reserve System, January 7, 2002.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 02-685 Filed 1-10-02; 8:45 am]

BILLING CODE 6210-02-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the

proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 4, 2002.

A. Federal Reserve Bank of Kansas City (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Lauritzen Corporation*, Omaha, Nebraska; to acquire 1.54 percent, for a total of 23.03 percent, of the voting shares of First National of Nebraska, Inc., Omaha, Nebraska, and thereby indirectly acquire additional interest in First National Bank of Omaha, Omaha, Nebraska; First National Bank, North Platte, Nebraska; Platte Valley State Bank & Trust Co., Kearney, Nebraska; Fremont National Bank & Trust Co., Fremont, Nebraska; First National Bank & Trust Company, Columbus, Nebraska; First National Bank, Overland Park, Kansas; First National Bank South Dakota, Yankton, South Dakota; First National of Colorado, Inc., Fort Collins, Colorado, First National Bank, Fort Collins, Colorado; Union Colony Bank, Greeley, Colorado; First National Bank of Colorado, Boulder, Colorado; First National of Illinois, Inc., Omaha, Nebraska, and Castle Bank, N.A., DeKalb, Illinois.

Board of Governors of the Federal Reserve System, January 7, 2002.

Robert deV. Frierson,
Deputy Secretary of the Board.

[FR Doc. 02-686 Filed 1-10-02; 8:45 am]

BILLING CODE 6210-02-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0282]

Medical Devices: General Principles of Software Validation; Final Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "General Principles of Software Validation." This document provides guidance to medical device manufacturers and FDA staff concerning requirements for validating software used within medical devices, in device production, or in implementing the manufacturer's quality system.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "General Principles of Software Validation" to the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John F. Murray, Center for Devices and Radiological Health (HFZ-340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4659.

SUPPLEMENTARY INFORMATION:

I. Background

This final guidance document entitled "General Principles of Software Validation" provides guidance to medical device manufacturers and FDA staff concerning requirements for validating software used within medical devices, in device production, or in implementing the manufacturer's quality system. It replaces the draft guidance that FDA issued for comment on June 9, 1997, and published in the **Federal Register** of July 25, 1997 (62 FR 40099).

We received responses from 36 organizations and individuals, with more than 650 questions, comments, and specific recommendations for changes to the guidance. However, further work on the guidance was interrupted by other high priority

activities, including implementation of the Food and Drug Administration Modernization Act of 1997, FDA's response to year 2000 software concerns, and two rounds of implementation of our first medical device performance standard. Because of the delay in issuing this final guidance, we have chosen to summarize our response to the comments received. As with any guidance, we will continue to accept comments and may update this document in the future.

The following summarizes the comments we received, and significant changes we made to the guidance in response to those comments:

A. Intended Scope

From a few of the comments received, it appears that some parties may not have realized the full breadth of the quality system regulation. The software validation requirement in 21 CFR 820.70(i) of the quality system regulation also applies to automated tools used to design medical devices and tools used to develop software. Since the first medical device good manufacturing practice regulation was published in 1978, there has always been an explicit validation requirement for software used in device production or used to implement the quality system. When design controls were introduced into the quality system regulation in 1997, that software validation requirement was extended to software used to design devices, such as computer-aided design and software development tools. FDA clearly addressed this issue at the end of its response to comment 136 in the preamble to the quality system regulation (61 FR 52602 at 52630, October 7, 1996). A copy of the text is included at the end of this section.

Some comments objected to the discussion of validation activities during the predesign "concept" phase of software development, both because the quality system regulation does not apply to research activities, and because there is too little information available at that point to make any validation related activity worthwhile. In response to these concerns, we have removed all reference to validation activities during the "concept" phase.

Other comments noted that the guidance covered more than just validation issues, and suggested changing the title to broaden the scope of the guidance. We acknowledge that the scope of the guidance is somewhat broader than the scope of validation in the strictest definition of that term. However, we have chosen not to change the title of the guidance. Planning,