

**RISNA**  
**RHODE ISLAND STATE**  
**NURSES ASSOCIATION**

*United for Excellence*

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October 26, 1999

Docket No. 99D-2335  
Dockets Mgt. Branch  
Division of Mgt. Systems & Policy  
Office of Human Resources & Mgt. Services  
Food & Drug Administration  
5300 Fishers Lane, Room 1061 (HFA 305)  
Rockville, MD 20852

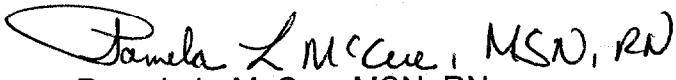
Dear sir:

Attached are the comments and suggestions from the Rhode Island State Nurses Association for the Medical Glove Guidance Manual.

If you have any questions, please contact me or Pat Molloy at the DOH, 401-222 2827, x102.

Thank you for your assistance.

Sincerely,

  
Pamela L. McCue, MSN, RN  
Executive Director

Patricia Molloy, MSN, RN  
Vice-President/RISNA

/mg

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98N-0313

## **1. Background/History**

The Universal Precautions of 1991 caused an increased use of protective gloves. As the demand for gloves increased, their quality went down. There is no known treatment for natural rubber latex allergy. Avoidance is the only effective treatment.

Studies show at least 8% of health professionals and up to 18% have natural rubber latex allergies. These allergies cause sensitization to everyday products made of latex such as: erasers, mouse pads, balloons, sneakers, toys, carpeting and foam pillows.

## **2. Response**

The Rhode Island State Nurses Association (RISNA) agrees with the reclassification of surgeons and patient examination gloves from Class I to II for increased safety and effectiveness due to stricter controls.

We also support the use of expiration dates supported by stability studies demonstrating acceptable physical and mechanical integrity during shelf life. However, while completion and compliance with new guidelines, RISNA suggests American Nurses Association (ANA) recommendations be followed to protect patients and personnel from latex allergy in all health care settings:

### **EXHIBIT I**

#### **Recommendations**

Therefore, the American Nurses Association recommends the following actions to protect patients and personnel from latex allergy in all health care settings:

1. Based on current research, all health care institutions should eliminate the unnecessary use of latex gloves and implement the use of low-allergen, powder-free latex gloves in all other settings.
2. Each facility shall convene a multi-disciplinary latex allergy task force to develop patient care guidelines to:
  - ensure that the environment is free of contamination by latex and other substances carried by glove powder;
  - identify latex-sensitized patients and those at risk, instruct them about self-care, and deliver latex-safe care in accordance with recommended practice guidelines;
  - establish an inventory of non-latex alternatives for latex medical devices;

- develop procedures to identify and resolve problems with medical devices relevant to allergic reactions or glove performance;
  - report allergic events related to latex medical devices to the Food 7 Drug Administration MedWatch program (phone 1-800 FDA-1088, Fax 1 800 FDA-0178).
- 3. Each health facility shall develop multi-disciplinary latex allergy occupational health guidelines that will:
  - ensure a workplace that is free of contamination by latex and other substances carried by glove powder;
  - educate personnel regarding latex allergy and related issues of hand care, hand dermatoses, glove use, product problem reports, and continued adherence to universal precautions;
  - provide task-appropriate, powder-free, low allergen gloves, and enlist manufacturers support to resolve glove-related problems;
  - facilitate early identification, diagnosis, treatment and tracking of personnel with hand dermatoses or symptoms of latex allergy;
  - report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1 800 FDA-1088, Fax 1 800 FDA-0178);
  - accommodate latex-sensitized employees safely in the workplace, assist disabled employees to obtain rehabilitation services, and direct disabled personnel to compensatory benefits when rehabilitation is not possible.
- 4. All health personnel shall:
  - be knowledgeable of latex allergy and its related issues;
  - implement latex allergy guidelines pertaining to the safety of patients and staff;
  - seek occupational health services and medical care for early diagnosis and treatment of hand dermatoses and symptoms suggestive of latex allergy and request documentation of glove-associated illness to OSHA;
  - report allergic events related to latex medical devices to the Food and Drug Administration MedWatch Program (phone 1 800 FDA-1088, Fax 1 800 FDA 0178);
  - be knowledgeable about employees' rights to workplace safety, reasonable accommodations for latex-sensitized personnel to remain employed, rehabilitation services, and compensatory benefits for disability when rehabilitation is not possible.

The Oregon Nurses Association was a pioneer in introducing legislation calling for exclusive use of low-latex protein, powder-free gloves for use in health care facilities. Additional states in which legislation has been introduced can be compared on Exhibit 2:

**EXHIBIT 2****LATEX ALLERGIES**

<b>Bill Number</b>	<b>Status</b>	<b>Bill Summary</b>
Indiana HB 1085	Intro. 1/6/98; passed the House Comm. on Public Health. 1998 reg. session adjourned 3/13/98; no carryover..	Prohibits the use by health care providers of powdered latex gloves.
Minnesota HB 2251	Intro. 5/18/97. 1998 reg. session adjourned 4/9/98; no carryover.	Limits the use of allergenic latex in health care facilities.
Nebraska LB 1090	Intro. 1/12/98. 1998 reg. session adjourned 4/14/98; no carryover..	Prohibits the use of powdered latex glove products.
New York AB 9541 S 5508	AB 954 intro 3/3/98. Substituted by S. 5508 6/19/98. Passed Senate 6/18/98. Passed Assembly 6/19/98. Signed by	Requires the Department of Health to review existing scientific research regarding allergic reactions to natural rubber latex, then issue guidelines for a latex management program in health care settings.

*A bibliography is available if interested.*

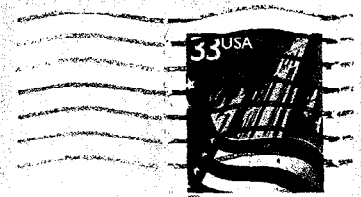
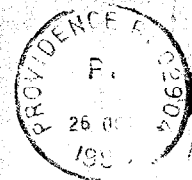
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