

FROM THE ACADEMY

American Academy of Dermatology's position paper on latex allergy

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In the past 10 years, allergy to natural rubber latex (NRL) products has become widespread within well-defined populations exposed to high levels of rubber. Affecting health care workers to children to housekeepers, this allergy has received significant attention. Latex and its additives, materials widely used in the manufacturing of protective barrier and medical equipment, as well as everyday household objects, have been identified as the causative agents of various types of dermatoses and other allergic reactions, including more severe anaphylactic reactions. The potential economic effects on workers' compensation and disability are large.

In response to the increasing incidence and awareness of both HIV and hepatitis virus in the late 1980s, the Centers for Disease Control mandated the adoption of "universal precautions," a standard of individual protection.¹ Use of personal protective equipment, such as latex gloves, became the standard of care. A dramatic increase in the incidence of latex allergy among health care professionals has mirrored the extensive adoption of these regulations. The Occupational Safety and Health Administration (OSHA) estimated that more than 5.6 million American health care workers use latex gloves on a regular basis resulting in more than 7 billion pairs of gloves consumed each year.²

Latex is a milky sap tapped from the rubber tree *Hevea brasiliensis*. It is often preserved with either ammonia or sodium sulfate; or it is purified and

vulcanized with sulfur to make rubber. Accelerators, such as thiurams, mercapto compounds, carbamates, and thioureas, may be used to decrease the production time in the manufacturing of NRL products, including gloves. Although gloves produced from other materials—such as vinyl—are available, the tactile qualities, comfort, barrier protection, and affordability of NRL gloves are superior. For similar reasons, NRL is used not only in glove manufacturing, but also as a constituent in other medical and household equipment.

TYPES OF ALLERGIES TO NRL PRODUCTS

There are three well-recognized reactions to NRL products: irritant contact dermatitis, allergic contact dermatitis, and immediate-type hypersensitivity reaction.

Irritant contact dermatitis results from the direct action of chemicals found in latex or other glove components on the skin; it is not directly mediated by the immune system. The extent of the reaction depends on other physical parameters, such as duration of exposure, skin occlusion, and skin temperature. Clinically, irritant contact dermatitis initially presents as erythema, pruritus, and edema, followed by lichenified, crusted plaques on the exposed areas.

A common reaction to NRL products is allergic contact dermatitis,³ also known as delayed-type hypersensitivity (type IV), and is caused by T-cell-mediated sensitization to the constituents of latex gloves, usually to the accelerators. Once sensitized, subsequent challenges from the same allergen will cause an eczematous dermatitis usually beginning within 48 to 72 hours. Clinical hallmarks include erythema, scaling, and vesiculation

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in the acute phase and lichenification in the chronic phase. Unlike an irritant contact dermatitis reaction, allergic contact dermatitis directly involves the interaction of the immune system and depends on a person's genetic susceptibility.^{4,5}

Immediate-type hypersensitivity (type I allergy), like allergic contact dermatitis, requires previous sensitization. This reaction is the most potentially dangerous reaction to NRL products, and deaths have occurred because of anaphylaxis. On re-exposure to the offending allergen, IgE linked to the latex protein directly induces the release of histamine and other chemical mediators. Clinical presentations vary among individuals and may include contact urticaria, burning or stinging, sneezing, coryza, conjunctivitis, dermatitis secondary to pruritus and scratching, asthma, and, with mucosal exposure, anaphylaxis.

TYPE IV ALLERGY: ROUTES OF EXPOSURE

Type IV allergy to rubber accelerators and antioxidants is an allergic contact dermatitis largely limited to the sites of direct contact of latex to the skin. In the case of NRL glove allergy, skin lesions are most commonly seen on the dorsum of the hand, the dorsum of the metacarpal-phalangeal joints, the thenar and hypothenar surfaces, the wrists, and the distal forearms. However, it is not uncommon to have reactions extending to areas adjacent to the site of NRL glove contact and occasionally to have more generalized skin involvement.^{6,7}

EPIDEMIOLOGY OF TYPE IV LATEX ALLERGY

Because the most severe latex reactions are caused by type I allergy, articles written in the medical literature on type I allergy far outnumber articles dealing with type IV allergy. In the past, it has been estimated that type IV allergy accounts for up to 82% of work-related allergic reactions to latex gloves³ and up to 84% of all occupationally acquired rubber allergy.⁸ Although these reactions are not life-threatening, they account for a significant decrease in work productivity and higher workers' compensation expenses. Type IV delayed hypersensitivity to NRL products is not generally caused by sensitivity to latex protein. Reactions occur to chemicals used in the manufacture of NRL articles including antioxidants and rubber accelerators. Three of the major groups of rubber

accelerators account for most of the allergic contact dermatitis to NRL gloves (ie, thiurams, carbamates, and mercapto compounds). One study estimated that type IV occupational allergy to NRL gloves was due to thiurams in 72% of cases, carbamates in 25% of cases, and mercapto compounds in 3% of cases.⁸ Cross-reactions between thiurams and chemically related carbamates are not uncommon.⁶

DIAGNOSIS OF TYPE IV ALLERGY TO NRL PRODUCTS

The standard for diagnosis of type IV delayed hypersensitivity to NRL products is a positive patch test to one or more of the chemical additives or to a piece of the NRL product. Both standard patch test screening series used in the United States contain standardized mixtures of chemicals found in latex products. The thiuram mix (1% in petrolatum) is a mixture of tetraethylthiuram monosulfide, tetramethylthiuram disulfide, tetraethylthiuram disulfide, and dipentaethylenethiuram disulfide. The mercapto mix (2% in petrolatum) is a mixture of mercaptobenzothiazole, *N*-cyclohexylbenzothiazyl sulfenamide, dibenzothiazyl disulfide, and morpholinyldibenzothiazole. Mercaptobenzothiazole (2% in petrolatum) is also on the series for individual testing. One study has suggested that mercaptobenzothiazole is the most sensitive marker for contact allergy to mercapto compounds.⁹ The carba mix (3% in petrolatum) includes 1,3-diphenylguanidine, zinc diethyldithiocarbamate, and zinc dibutyldithiocarbamate.

Type IV latex allergy is a form of delayed hypersensitivity. Attention should be paid to the timing of the cutaneous reaction in relation to the time of exposure. Typically, a patient with delayed hypersensitivity to latex will experience reactions beginning 48 to 72 hours after exposure. However, type IV reactions can begin as quickly as 8 hours after exposure or as long as 5 days after exposure.⁷ When type IV allergy to latex is suspected, the patient should undergo patch testing to rubber accelerators including thiuram mix, mercapto mix, carba mix, and mercaptobenzothiazole. These testing allergens are present on the most widely used standard patch test screening trays. Patch testing with a thin piece of an NRL product (eg, glove) can sometimes be helpful in confirming contact allergy, but it is not recommended in patients with

suspected type I allergy to NRL. In addition, most standard patch test trays include the antioxidant, black rubber *para*-phenylenediamine (PPD) mix, which is responsible for contact allergy to some black rubber objects such as the black rubber bulb on blood pressure instruments or the black rubber used to line automobile windows. The black rubber PPD mix (0.6% in petrolatum) includes *N*-isopropyl-*N*-phenyl-4-phenylenediamine, *N*-cyclohexyl-*N*-phenyl-4-phenylenediamine, and *N,N*-diphenyl-4-phenylenediamine.

Some medical centers specializing in patch testing have more extensive rubber screening patch test trays that include antioxidants and accelerators such as naphthyl compounds, thioureas, dodecylmercaptan, and monobenzylether of hydroquinone. For completeness, testing should also probably be done for two antioxidants, 4,4'-thiobis(6-tert-butyl-meta-cresol) (Lowinox 44S36) and butylhydroxyanisole (BHA), which have been reported to cause allergy to some latex examination gloves.¹⁰

TYPE I ALLERGY: ROUTES OF EXPOSURE

Type I NRL allergy can be triggered by contact with latex antigen via cutaneous, percutaneous, mucosal, and parenteral routes of delivery.¹¹ The majority of systemic anaphylactic reactions occur after mucosal or parenteral exposure. Products that may contain NRL are listed in Table 1.

Mucosal latex exposure can occur from airborne powder particles, used as dry lubricant on gloves. The powder is adsorbent and acts as a carrier for the latex proteins in the air. These particles can be dispersed when removing gloves and cause aerosol contamination, resulting in occupational asthma and occasionally type IV allergic contact dermatitis.¹²

In addition, patients with type I NRL allergy can have a cross-reaction to certain foods. Avocado, potato, banana, tomato, chestnut, kiwi, and papaya were found to elicit a positive skin-prick test more commonly in type I NRL-allergic persons as compared with both atopic and nonatopic controls.^{11,13} Although most of the patients tested did not have a clinical problem with food allergy, 8 of 47 NRL-allergic patients (17%) had anaphylactic reactions to food (banana, avocado, tomato, or kiwi).¹⁴ In addition, some type I NRL-allergic patients experienced local irritation when working with such foods.

Reports of intraoperative anaphylaxis have also been described. This was recognized in the early 1990s, when anaphylactic reactions to the NRL balloon during barium enema examinations was reported to result in patient deaths.¹⁵ One report describes 15 patients with either spina bifida or congenital urologic abnormalities who have experienced 19 episodes of intraoperative anaphylaxis; all patients tested positive by skin-prick test and radioallergosorbent assay (RAST) for NRL allergy.¹⁶ Another report describes five women who sustained intraoperative anaphylaxis—3 had a history of fruit allergy and all had known contact urticaria to NRL. When tested with skin-prick tests with anesthesia, all were negative; when tested with skin-prick tests for NRL allergen, all were positive.¹⁷

EPIDEMIOLOGY OF TYPE I LATEX ALLERGY

Type I NRL allergy is most commonly recognized in those who have high levels of exposure to NRL products. It has been suggested that an increased demand for latex gloves worldwide forced a modification in manufacturing, thereby creating a potentially more allergenic product, which may have sensitized more people.^{18,19} In addition, the prevalence of NRL allergy appears to be increasing as more physicians are recognizing the condition.

For health care workers, agricultural workers, and housekeepers, the main exposure to NRL is through rubber gloves. Other groups at high risk for the development of type I NRL allergy include rubber industry workers, persons with hand dermatitis, atopic patients, children with spina bifida or urogenital abnormalities, and other patients who need frequent surgery.²⁰

Several studies have been performed to estimate the prevalence of type I NRL allergy. However, obtaining an exact figure is confounded by the lack of a definitive test. Although the Food and Drug Administration (FDA) has approved four serum tests for latex-specific IgE (AlaSTAT, Immolite, Pharmacia CAP, and HY-TEC), there is still no universally accepted standardized test to assess type I NRL-allergic persons. Attempts to assess the potential of NRL allergy in the general population revealed positive antibody titers in 6.4% of volunteers, with 2.3% testing strongly positive for anti-latex IgE.²¹

Researchers from various countries have

Table I. Products that may contain latex⁵⁸

Medical devices	Household and consumer products
Anesthesia, ventilator circuits, bags	Wound dressings
Band-Aid adhesive strips	Art supplies (paints, glue, erasers, fabric paints)
Bed protectors (washable rubber)	Automobile tires
Blood pressure cuff, tubing	Balloons
Bulb syringe	Balls (tennis balls, bowling balls)
Catheters	Carpet backing, gym floor, basement sealant
Disposable gloves	Clothes, T-shirt appliqué, sock elastic, underwear, sneaker soles, sandals
Elastic wraps	Condoms, contraceptive diaphragm
Electrode bulbs, pads, grounding	Crutches: Tips, axillary pads, hand grips
Endotracheal tubes, airways	Dental dams, cups, bands, root canal material
Gastric tubes, buttons	Diapers, incontinence pads, rubber pants
IV access: Injection ports, Y-sites, bags, buretrol ports, adapters, needleless systems	Expandable fabric (waistband)
OR masks, hats, shoe covers	Feeding nipples
Oxygen masks, cannulas	Food handled with latex gloves
Manual resuscitators	Handles on racquets, tools
Medication vial stoppers	Hot water bottles
Penrose surgical drains	Infant toothbrush-massager
Pulse oximeters	Kitchen cleaning gloves
Ready-to-use enemas	Kiwi, banana, avocado, other fruits
Reflex hammers	Newsprint, advertisements, coupons dusted with latex
Respirators	Pacifiers
Rubber aprons	Rubber bands, bungee cords
Soft casts	Toys
Stethoscope tubing	Water toys and equipment (beach thongs, masks, bathing suits, caps, scuba gear, goggles)
Suction tubing	Wheelchair cushions, tires
Syringes	Zippered plastic storage bags
Tapes	
Tourniquets	
Tubing, sheeting	
Vascular stocking	

OR, Operating room.

employed numerous methodologies to estimate the prevalence of type I NRL-allergic hospital workers. In one study, 104 of 342 health care workers (30%) were determined to be type I NRL-allergic via interviews, skin-prick testing with rubber glove extract, and/or measuring latex-specific IgE antibodies.²² Another study found 15 of 512 (2.9%) hospital employees to be type I NRL allergic, as confirmed by skin-prick and NRL, use-tests.²³

However, results more consistently show a range of between 6% and 17% of health care workers at risk for type I NRL allergy.²⁴⁻²⁹ Assuming more than 5.5 million United States health care workers,³⁰ one may estimate that between 330,000 (6%) and 935,000 (17%) health care employees are at risk for type I NRL-associated reactions.

Agricultural workers and housekeepers also use rubber gloves daily. Studies estimate a prevalence of type I NRL sensitization for these groups similar to that of hospital personnel: 20% of atopic housekeepers had positive NRL skin-prick tests,³¹ whereas 18% of greenhouse workers who wore latex gloves had symptoms of immediate-type hypersensitivity.³² There have been reports of occupational asthma affecting plant workers involved in the manufacturing of dolls³³ and surgical gloves³⁴ with NRL.

Children with spina bifida have been shown to have a high prevalence of IgE-mediated hypersensitivity to NRL. Mucosal absorption of different latex antigens early in life during multiple surgical procedures has been postulated to result in type I sensitization to NRL.³⁵ The number of operations and a person's history of atopy correlated with the

presentation of type I NRL allergy in patients with spina bifida.³⁶ In surveys of myelodysplasia clinics, studies report between 0% and 22% of children experienced type I NRL allergy compared with 1.1% of controls.^{37,38} Another study of 50 patients with spina bifida found 60% to have a type I NRL allergy as defined by history, NRL RAST, and/or skin-prick test.³⁹ Using the RAST test to assess type I NRL allergy, several studies have reported between 34% and 65% of children with spina bifida are positive for type I NRL allergy.⁴⁰⁻⁴²

Hand dermatitis and atopy have also been identified as risk factors for NRL allergy. One study found 60 of 306 atopic children (20.8%) to have positive tests for anti-latex IgE, whereas only 1 of 303 nonatopic children (0.3%) had positive antibodies.⁴³

DIAGNOSIS OF TYPE I LATEX ALLERGY

The suspected NRL-allergic patient should be carefully questioned regarding symptoms temporally related to exposure to purported NRL agents. Specifically, the diagnosis of NRL allergy should be suspected in high-risk patients and in anyone who has a history of urticaria or angioedema of the lips when inflating balloons; itching, burning, or urticaria when donning latex gloves; history of adverse reactions to barium enema examinations; or urticaria or other systemic symptoms occurring after exposure to other latex devices (especially during medical or surgical procedures). The temporal presence of signs or symptoms of NRL allergy during or shortly after exposure should alert physicians to the possibility of type I NRL allergy. Patients can be screened with a RAST to detect latex-specific IgE. If the RAST is positive (ie, IgE antibodies are detected), no further testing should be done. If negative (because RASTs may have a false-negative rate of > 30%), a "use" test utilizing a latex glove in a supervised setting may be performed, first with one finger, then an entire hand. If still negative, a skin-prick test should be done with eluted latex protein in solution. A standard latex allergen extract for skin testing is not currently available in the United States. Use tests and skin-prick tests should be performed in a setting with life support equipment available because anaphylactic reactions can occur. The presence of a wheal at the test site indicates NRL hypersensitivity when compared with positive and negative con-

trols. This test must be performed under close and experienced supervision because anaphylactic reactions in response to a skin-prick test have been reported.^{44,45} It should be noted that RASTs performed soon after anaphylaxis or a severe allergic reaction may show a false-negative result because of consumption of IgE.

TREATMENT AND PREVENTION OF LATEX ALLERGY

Irritant contact dermatitis to NRL gloves is mostly due to moisture, heat, and friction under the glove. Studies have shown that use of a soft, breathable glove liner (eg, cotton liners) under NRL gloves can help minimize this problem. Other useful measures include reducing exposure to other irritants, using minimally irritating skin cleansers, and treatment with topical corticosteroids. For persons with irritant dermatitis caused by clothing, soft lining and other measures to reduce friction are helpful. Although irritant dermatitis to rubber cannot always be eliminated, measures such as these will often help to minimize the problem enough to be successful for the patient.

In contrast, many problems with type IV allergy to NRL gloves can be entirely eliminated. Patch testing should be done to identify the specific rubber accelerator or antioxidant causing the patient's problem. Once identified, the patient can often use alternative rubber articles that utilize different rubber manufacturing chemicals. For example, a patient with a contact allergy to thiurams will often be able to tolerate latex made with mercapto compounds. That is, persons with type IV allergy to NRL can often continue to use NRL materials if they are carefully chosen. Reference articles are now available that list the specific accelerators used in the manufacture of different brands of latex gloves.^{3,46} Corticosteroids (topical and systemic) are the mainstay of treatment.

All type I NRL-allergic patients should be educated regarding the identification and avoidance of NRL products in the home and in the workplace. At a minimum, nonlatex glove alternatives should be provided to health care workers who have type I reactions to NRL, and low-allergen, powder-free gloves, if tolerated, should be worn by other health care workers at that worksite. Estimates of the type I latex allergen content of medical gloves and other rubber objects can be found in the litera-

ture.⁴⁷ Patients with type I NRL allergy are treated with antihistamines and bronchodilators for respiratory symptoms. When type I reactions present as dermatitis secondary to scratching, topical steroids are useful.

For persons who need to avoid NRL, review articles can be found in the medical literature listing alternatives that can be safely used.⁴⁸ It is important to emphasize that synthetic rubber gloves are acceptable for persons with type I NRL allergy; however, these gloves still may contain substances that can induce a type IV allergic reaction. Most persons with type IV NRL glove allergy can find alternative NRL gloves that use accelerators to which they are not allergic. However, there will be some persons who will be unable to find suitable NRL alternative gloves or even nonlatex gloves because they contain additives to which the person is allergic. For these individuals, vinyl gloves may be an acceptable substitute for many nonsterile procedures. However, several studies have shown that vinyl gloves may leak more readily than NRL gloves and may not always provide an acceptable barrier for exposure to blood and bodily fluids.⁴⁹⁻⁵² Double-gloving with vinyl gloves may provide greater protection during the performance of mucosal examinations (eg, oral, rectal, vaginal). Thermoplastic elastomer gloves are more expensive but have been found to provide a barrier that is as effective as NRL gloves for high-risk exposure.⁵³

The epidemic of HIV has also made it necessary to provide society with a means of safe sexual contact. Contact allergy to latex condoms has become a significant problem. Natural-membrane condoms provide an alternative; however, they will not prevent the spread of disease.⁵⁴ Persons with type IV allergy to NRL can often find alternative condoms that do not contain the accelerator to which they are allergic.⁵⁵ The previously mentioned articles that provide latex alternatives can be helpful. Recently, polyurethane condoms for both men and women have become available and will provide protection for individuals unable to use latex condoms.⁵⁶

RECOMMENDATIONS

The American Academy of Dermatology strongly suggests implementation of the following measures directed at reducing the incidence of latex-related allergy.

1. Every pre-placement interview for jobs that

require exposure to NRL products should include inquiries into an employee's history with NRL products. Suspected NRL-allergic persons should be offered the option of further diagnostic testing. The history should pay careful attention to risk factors, symptoms, and the distribution of cutaneous lesions. Persons with systemic symptoms and other noncutaneous symptoms should first be offered type I allergy testing. Likewise, individuals with skin lesions that occur within 24 hours of exposure to NRL should initially be offered type I allergy testing. Those individuals with skin lesions that occur more than 24 hours after exposure to NRL should first be offered type IV allergy testing. Because some persons will experience more than one type of reaction, it is prudent to test everyone with symptoms for both types of allergy to NRL products.

2. All medical and dental facilities should offer latex-safe environments for patients with NRL allergy. Hospitalized patients should have histories that include questions on history of NRL allergy. All patients who have undergone or will require multiple surgical procedures, such as patients with spina bifida, and patients with a history suggestive of NRL allergy should be offered procedures in a latex-safe environment. In addition, charts and bedsides should indicate the allergic status of the patient in the hospital. If necessary, prophylactic medications, including nonsedating antihistamines and systemic corticosteroids, may be indicated for severely allergic patients. However, these do not guarantee that an anaphylactic reaction will not occur. A latex-safe environment means the following: (1) No one in the area should wear NRL gloves with powder; (2) only nonlatex gloves should be used to directly examine the patient; (3) all NRL objects that *routinely* directly or indirectly come into contact with mucosa, nonintact skin, and internal bodily spaces (eg, catheters, medical neopoppers, endotracheal tubes) should be removed or made latex-safe (eg, by covering); (4) products made of dry molded NRL (eg, wheelchair tires, tool handles) do *not* need to be removed from the area. If direct contact with such objects is routine, precautions should be taken to minimize direct exposure by covering the object or body part exposed (ie, having the patient wear nonlatex gloves while wheeling

- self in wheelchair); and (5) much like diabetic or low-fat diets, hospital dietary services should have latex-safe meals that lack food known to cross-react with antibodies to NRL. All hospitals should also have latex-safe equipment carts available. If possible, hospitals should have one operating room that is always latex-safe. If this is not possible, surgery on latex-allergic patients should be scheduled as the first procedure of the day so that latex-allergens cannot build up in the environment.
3. All type I NRL-allergic patients should be educated regarding identification and avoidance of NRL products in the home and in the workplace. A list of potentially cross-reacting foods should be provided to the patient. These patients should also wear medic-alert bracelets to avoid inadvertent exposure during medical emergencies, and they should carry an epinephrine injection device (Epi-pen) in case such exposure occurs.
 4. All medical and dental facilities are encouraged to exclusively use powder-free gloves with low NRL antigen levels. For example, it has been shown that replacing high-allergen NRL gloves with low-allergen alternatives in an operating room can decrease the level of NRL aeroallergen by more than 10-fold (the effect of powder vs powder-free gloves was not examined in this study).⁵⁷ It should be emphasized that "hypoallergenic gloves" may not be safe for either latex-allergic or rubber accelerator-allergic patients. "Hypoallergenic gloves" may mean that they do not contain any glove powder or may not contain one of a myriad of rubber accelerators. For this reason, on Sept. 30, 1997, the FDA published a rule, requiring manufacturers to remove the hypoallergenic claim from the labeling of any device that contains NRL, effective Sept. 30, 1998.
 5. All medical facilities should consider using latex-safe operating rooms for trauma surgery because proper screening of these patients is not usually feasible. Similarly, emergency rooms should be latex-safe with properly prepared latex-safe crash carts.
 6. All medical facilities should be encouraged to provide vinyl or other non-latex gloves for general physical examinations, especially for all *mucosal* examinations (eg, oral, vaginal, rectal).
 7. Because most serious reactions result from mucosal exposure to latex antigens, all food preparation services (eg, hospital cafeterias, food processing plants, restaurants) should be encouraged to use only nonlatex gloves to prepare food.
 8. Health care facilities should be encouraged to develop a multidisciplinary latex allergy committee to address the following issues: educational programs for employees, procedures relating to occupational latex allergy (eg, reassignment of severely allergic employees, workman's compensation issues), policies of evaluating and managing latex-allergic patients, and plans for high-risk areas such as emergency rooms and operating suites.

FUTURE GOALS

In today's modern world, NRL is ubiquitous. A brief glance at the products listed in Table I demonstrates that hundreds of everyday goods, particularly those used in the health care environment, use NRL in manufacturing.

Eliminating the use of NRL, therefore, is not a viable option. However, the scope of the NRL-allergic population warrants several improvements in the manufacturing and use of NRL products in the workplace. Manufacturers are already researching and producing disposable gloves with low allergen levels; manufacturers of other NRL-containing products must follow this trend. Latex-free substitutes must be made available to patients and employees. In addition, manufacturers should be required to adopt a uniform cautionary statement on the labeling of all devices that contain NRL. On Sept. 30, 1997, the FDA published its labeling requirements for all *medical* devices that contain NRL. The FDA has also published draft guidance for manufacturers of NRL medical devices that wish to make claims in the product labeling about the reduced potential of type IV hypersensitivity.⁵⁸

Finally, there needs to be progress in the methodologies used to identify the type I NRL-allergic patient. We need a standardized skin-test extract to assess type I NRL-allergic patients. Once NRL-allergic patients and NRL-containing

⁵⁸Food and Drug Administration. Guidance on the content and format of premarket notification [510 (k)] submissions for testing for skin sensitization to chemicals in latex products. Draft document issued July 28, 1997.

products are uniformly identified, health care providers can begin to control this NRL allergy "epidemic."

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