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Target Audience
 All HSE Inspectors
 EMAS
 SG Occupational Hygiene Inspectors

NATURAL RUBBER LATEX SENSITISATION IN HEALTHCARE

This SIM informs inspectors of: the sensitisation risk associated with natural rubber latex (NRL), the application of the Control Of Substances Hazardous to Health Regulations; details of a recent civil case relating to NRL gloves & COSHH; provides guidance on enforcement; and identifies sources of guidance on the risks of natural rubber latex

BACKGROUND

1. Natural rubber latex (NRL) can be found in many products within healthcare. It has been extensively used in the manufacture of medical gloves (non sterile examination gloves, surgical gloves) because it is a very durable and flexible material giving wearers a high degree of dexterity, sensitivity and microbiological protection. It is also used in a range of medical devices. As the use of such products has increased, particularly the increased use of single use gloves in infection control, NRL allergy and sensitisation has been identified as a problem.

THE PROBLEM

2. NRL exposure can lead to a number of health problems including:

- **Irritation**, the symptoms of which include redness, soreness, dryness or cracking of the skin in areas exposed to NRL. This type of reaction is not an allergic response. Once the irritant agent has been identified and its use discontinued, the symptoms will disappear and not reoccur:
- **Type I allergic reactions**, the symptoms of which include localised or generalised rash (urticaria), inflammation of the mucous membranes in the nose (rhinitis), red and swollen eyes with discharge (conjunctivitis) and asthma-like symptoms. This is an allergic response to the extractable latex proteins and occurs almost immediately on contact. In rare cases it may result in anaphylactic shock. These reactions can occur as a result of skin contact with NRL or inhalation of latex proteins through the use of powdered NRL gloves;
- **Type IV allergic reactions**, the symptoms of which include dermatitis and itching with oozing red blisters, which is usually localised to sites of exposure. It occurs between 10-24 hours after exposure and can get worse over the subsequent 72 hours. This is an allergic response to the chemical additives, known as accelerators, used in the

manufacture.

3. Increasing numbers of cases of asthma and contact dermatitis attributed to NRL have been reported to the Occupational Disease Intelligence Network since the 1990s. There are a number of possible reasons for this: increasing awareness of the problem; increased use of NRL gloves and other equipment; and/or changes in the type of NRL gloves used. The figures from ODIN do not reflect the true extent of the problem, in that the Consultants who provide data for ODIN would not see all cases.

NRL IN HEALTHCARE PRODUCTS

4. The majority of healthcare products containing NRL are 'medical devices' as defined by the Medical Devices Regulations 1999. Therefore their manufacture and provision are regulated by the Medicines & Healthcare Products Regulatory Agency (previously the Medical Devices Agency). The Supply of Machinery (Safety) Regulations 1992 specifically exempt medical devices. Presently there is no standard under the Medical Device Regulations defining the labelling of NRL containing products. There are discussions at both European & International levels to determine the requirements for the labelling, however this is unlikely to be finalised for some years.

5. **Single use disposable gloves.** The use of gloves as part of infection control within healthcare has risen exponentially during the 1990s. There are a number of different types of gloves available. NRL gloves may be powdered, to make them easier to get on and off, or non-powdered. There are also some types of single use disposable glove that are lubricated with substances such as aloe vera. The protein content in NRL gloves also varies. If there is prolonged and close skin contact all NRL gloves present a risk of skin sensitisation. However the risk is reduced in gloves with lower levels of latex proteins and process chemicals. The proteins in the NRL glove leach into the powder, which becomes airborne when the gloves are removed. This creates a risk of a respiratory or asthma reaction to the user and to sensitised individuals in the vicinity. This risk is almost completely eliminated in powder free gloves with lower levels of latex proteins and process chemicals. Glove powder has also been identified as a risk to patients, to those sensitised to NRL and as a causative agent in the formation of abdominal adhesions and starch granuloma during surgery.

6. **Other Medical Products.** NRL is not only contained within single use disposable gloves, but can also be found in a number of medical products, such as catheters, condoms, elasticised bandages, wound dressings, etc. It can also be found in the packaging for a number of medical products. While these may pose a low risk of sensitisation, they can pose a significant risk (e.g. anaphylactic shock) to sensitised individuals, either patients or healthcare workers.

THE APPLICATION OF THE CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS TO NRL

7. NRL is a substance hazardous to health and so COSHH applies. It is a respiratory sensitiser and a major cause of occupational asthma. An assessment of the risks to health created by work involving NRL should be undertaken (regulation 6). Exposure to NRL should be prevented or, where this is not reasonably practicable, it should be adequately controlled. (COSHH regulation 7).

8. *Dugmore v Swansea NHS Trust (& another)* [2002] EWCA Civ 1689, concerns a civil claim for damages by an employee who had developed an allergy to NRL as a result of wearing NRL gloves. The plaintiff, a nurse, developed a latex allergy during 1993 to 1995

as a result of wearing NRL gloves while working for the first defendant. She was atopic, and thus susceptible to the development of such an allergy. The allergy had become apparent in a serious episode in June 1996, after which she was provided with PVC gloves. She continued to be provided with such gloves when she moved in 1997 to work for the second defendant. In December that year she suffered anaphylactic shock after handling a box which had contained NRL gloves, and had been unable to work as a nurse since. The Court of Appeal held that the second defendant was not liable. The Court found against the first defendant on the basis that they were in breach of the 7(1) duty in 1996.

9. The judgment has been interpreted in some quarters to mean that the use of NRL gloves is illegal. This is NOT the case. The circumstances of the Dugmore case demonstrated that it was reasonably practicable in that case to prevent exposure. This does not suggest that this is reasonably practicable in all cases. The Lords specifically commented, "Latex is so commonly used in so many products that its total elimination can scarcely be thought practicable". In terms of adequately controlling the risks of NRL from gloves it was stated "it cannot be adequate control to oblige an employee frequently to wear powdered latex gloves when other barriers are available".


HEALTH SURVEILLANCE FOR SINGLE USE DISPOSABLE NRL GLOVES

10. Single use disposable NRL gloves provide the majority of exposure to NRL. As NRL produces a risk of asthma & dermatitis health surveillance is appropriate. The extent and detail of the health surveillance should be related to the degree of risk identified during the COSHH assessment & determined in consultation with an occupational health professional.

Health surveillance for non-powdered low protein gloves should include:

- An assessment of the worker's respiratory health & skin condition before they start a relevant job to provide a baseline record.
- A regular (at least annual) enquiry for dermatitis and asthma. Such an enquiry might be undertaken by written questionnaire, verbally during appraisal reviews etc. Positive results should be referred to an Occupational Health professional for assessment.
- A responsible person identified and known to staff, competent to deliver these duties, and with lines of referral to an occupational doctor or nurse, for the reporting of symptoms as they might occur.
- For staff known to be sensitised to NRL and those considered to be at a high risk of developing sensitisation i.e. atopic individuals, a higher level of health surveillance including a periodic clinical assessment by an occupational health doctor or nurse will normally be deemed appropriate.
- A record of the health surveillance

INSPECTOR ACTION

11. Inspectors are asked to assess the management of NRL in terms specifically of the risk of asthma. General guidance is contained in [FOD Inspection Pack - Asthmagens](#) .

12. Inspectors should ensure that an assessment of the risks from single use disposable NRL gloves is undertaken.

- Preventing exposure by, for example, having a policy of only wearing gloves where

there is a risk of infection

- That where a risk of infection requires hand protection, staff should only wear NRL gloves where there is a clear operational need, substituting nitril, polyurethane or vinyl gloves where practicable.
- Employers may assess that there is still an operational need for NRL gloves due to their superior microbiological barrier protection, sensitivity & elasticity over other glove materials. However as standards of manufacturing of alternative substances improve, this argument is reducing. A number of NHS Trusts have already completely withdrawn NRL gloves across all areas, including surgery.

13. Other protective measures likely to be identified by a suitable and sufficient risk assessment should include the following:

- having a general policy on NRL use;
- where NRL gloves are assessed as absolutely necessary, purchasing policies specifying single use NRL gloves with as low a level of extractable (or leachable) protein as reasonably practicable (manufacturing standards of less than 50µg/g are reasonably achieved) and that are powder free (at or below 2mg per glove).
- ensuring that the general policy on NRL covers the action needed to protect staff who are sensitised to NRL. This may include staff being provided with gloves made of an alternative material to NRL, and reviewing the risks to their health from contact with other NRL products. These individuals should not be required to work in areas where powder particles from NRL gloves are likely to become airborne. The policy should also address how NRL-sensitised patients are managed.

APPLICATION OF EMM TO NRL

14. At present there is no specific guidance on the application of the Enforcement Management Model to sensitisers in general or NRL in particular. General guidance on the application of EMM to health issues is contained in [OC130/5](#). Guidance on the application of EMM to chemicals is contained in [OC273/19](#)

15. The application of the EMM is considered in terms of its respiratory sensitisation risk alone. It should be acknowledged that NRL is also a potential dermatitis risk.

16. Gap analysis. **Actual Risk:** In circumstances where Inspectors identify the wearing of powdered 'high protein' NRL gloves as part of 'universal precautions' in the management of infection control, this would result in a '**serious health effect**' consequence – analogous to a serious personal injury. 'Repeated or prolonged exposure' from wearing NRL gloves would result in '**possible**' likelihood of injury. The **benchmark** for exposure to asthmagens, in circumstances where the risks are adequately addressed by elimination / substitution of NRL is '**nil**' or '**negligible**'. The risk gap is therefore **extreme**

Standard: There is a significant wealth of research to demonstrate the risks of powdered high leachable protein NRL gloves to respiratory health. This policy line will be expounded in the revision of the HSE leaflet 'Latex & You'. The standard should therefore presently be viewed as **Interpretive**

17. Initial Enforcement Expectation:

Where inspectors identify those circumstances as described in para 16 the initial


enforcement expectation is that of **improvement notice**.


18. Strategic Factors: Inspectors may wish to consider that action to improve the management of NRL risk is in the public interest. Action would result in a benefit to the wider community, as staff sensitised to NRL can often not continue to work in the same environments, so losing valuable resources to the NHS to deliver patient care. There are a number of 'pressure groups' active in this topic area, setting an expectation upon HSE for action. The effective management of NRL protects vulnerable groups both within the working population and patients. Any action will have a positive and long-term effect upon the dutyholder, the geographical area, and the sector.

REPORTING ON FOCUS

19. Guidance on the recording of asthmagens inspections, including the completion of the risk control indices is contained in the [FOD Inspection Pack - Asthmagens](#) 

GUIDANCE & SOURCES OF INFORMATION

20. The HSE leaflet INDG320 '[Latex & You](#)'  will be revised in line with the information in this SIM & re-issued to coincide with European Week of Health & Safety 2003.

21. Many NRL containing products within healthcare are 'medical devices' and therefore guidance is produced by the Medicines & Healthcare Products Regulatory Agency (previously the Medical Devices Agency). [Device Bulletin 9601 Latex Sensitisation In Healthcare Settings \(Use of Latex Gloves\)](#) or [Safety Notice 9825 Latex Medical Gloves \(Surgeons & Examination\): Powdered Latex Medical Gloves \(Surgeons & Examination\)](#) 

22. Guidance on the provision of occupational health may be found in: HSE Guidance note MS 24: Medical Aspects of Occupational Skin Disease; MS 25: Medical Aspects of Occupational Asthma.

23. The [Latex Allergy Support Group](#), set up & run to support sensitised individuals, has been campaigning to increase awareness of latex allergy. Through its Latex Summits it has brought together manufacturers, suppliers, regulatory bodies, users etc. A record of the meetings of the Latex Summits can be found at: [Latex Summit: Meeting of Minds](#) and [Latex Summit 2: Leadership & Responsibility](#)

24. HSE is coordinating the production of guidance on latex allergy in partnership with: Latex Allergy Support Group, Royal College Of Nursing, Medicines & Healthcare Products Regulatory Agency, Industry representatives through the Association of British Healthcare Industries, UNISON, National Patient Safety Agency. The aim is to provide an educational resource suitable for: employers; employees, patients, and manufacturers. It will be launched during European Week of Health and Safety in October 2003 and initially will be available as a leaflet and CD-rom a web-based version will be released later.

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