

# **Higher National Unit specification**

#### **General information**

**Unit title:** Local Decontamination of Re-usable Instruments

**Unit code:** H485 34

Superclass: PL

Publication date: May 2013

**Source:** Scottish Qualifications Authority

Version: 01

## **Unit purpose**

This Unit has been designed to enable candidates to develop the knowledge and skills required to recognise the importance of decontamination in preventing the spread of infection. It will also enable candidates to apply their knowledge and skills to ensure reusable instruments are safely and effectively decontaminated in accordance with national guidance for local decontamination. The Unit will focus on national guidance relevant to facilities, equipment, processes and management.

It is suitable for individuals who undertake decontamination activities or supervise decontamination activity within their workplace.

### **Outcomes**

On successful completion of the Unit the learner will be able to:

- 1 Explain the importance of decontamination in preventing the spread of infection.
- 2 Explain the principles and elements in the decontamination life cycle of re-usable instruments.
- 3 Explain the requirements for compliance in relation to current local decontamination guidance.
- 4 Process instruments successfully through the key stages of local decontamination.

## **Credit points and level**

1 Higher National Unit credit at SCQF level 7: (8 SCQF credit points at SCQF level 7)

# **Higher National Unit specification: General information (cont)**

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## **Recommended entry to the Unit**

Entry is at the discretion of the centre. It is recommended that candidates either undertake decontamination activities in their workplace or have supervisory responsibility for decontamination activity within their area.

### **Core Skills**

Opportunities to develop aspects of Core Skills are highlighted in the Support Notes for this Unit specification.

There is no automatic certification of Core Skills or Core Skill components in this Unit.

# **Context for delivery**

If this Unit is delivered as part of a Group Award, it is recommended that it should be taught and assessed within the subject area of the Group Award to which it contributes.

This Unit is an optional Unit within the framework of the HND in *Dental Nursing*. It may also be delivered as a stand alone Unit for Continuing Professional Development purposes, eg within other primary care environments who undertake the local decontamination of instruments.

# **Equality and inclusion**

This Unit specification has been designed to ensure that there are no unnecessary barriers to learning or assessment. The individual needs of learners should be taken into account when planning learning experiences, selecting assessment methods or considering alternative evidence.

Further advice can be found on our website www.sqa.org.uk/assessmentarrangements

# **Higher National Unit specification: Statement of standards**

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Acceptable performance in this Unit will be the satisfactory achievement of the standards set out in this part of the Unit specification. All sections of the statement of standards are mandatory and cannot be altered without reference to SQA.

Where evidence for Outcomes is assessed on a sample basis, the whole of the content listed in the Knowledge and/or Skills section must be taught and available for assessment. Learners should not know in advance the items on which they will be assessed and different items should be sampled on each assessment occasion.

### **Outcome 1**

Explain the importance of decontamination in preventing the spread of infection.

### Knowledge and/or Skills

- Importance of infection prevention and control in relation to decontamination
- Staff and patient safety
- ♦ Infective agents of significance
- ♦ Infections/diseases caused by inadequate decontamination
- Routes of transmission
- Principles and methods of decontamination (cleaning, disinfection and sterilisation)
- Risk assessment

#### Outcome 2

Explain the principles and elements in the decontamination life cycle of re-usable instruments.

### Knowledge and/or Skills

- Key stages of the decontamination life cycle
- Health and safety and infection control requirements
- Acquisition
- ◆ Use
- Transport
- Cleaning principles and processes
- Disinfection principles and processes
- Sterilisation principles and processes
- Inspection and packaging
- Storage
- Disposal
- Ensuring quality
- ♦ Types of local decontamination equipment (ultrasonic cleaners, washer disinfectors, Type N sterilisers and Type B sterilisers), their operating principles and periodic testing
- ◆ Training
- Documentation

# **Higher National Unit specification: Statement of standards (cont)**

**Unit title:** Local Decontamination of Re-usable Instruments

### **Outcome 3**

Explain the requirements for compliance in relation to current local decontamination guidance.

### Knowledge and/or Skills

- Medical Device Regulations
- Health and Safety at Work Act
- Health and safety policies and guidance in relation to infection control
- Decontamination standards, legislation, policies and guidance
- ♦ Challenges to achieving successful local decontamination
- Requirements for Local Decontamination Units (LDUs):
  - Layout
  - Design
  - Workflow
  - Equipment
- ♦ Best practice in local decontamination
- Roles and responsibilities of key personnel defined in Scottish Health Technical Memorandums 2010 and 2030
- Training requirements for staff involved in local decontamination
- Documentation
- Management requirements
- Quality management systems

#### **Outcome 4**

Process instruments successfully through the key stages of local decontamination.

### Knowledge and/or Skills

- Risk assessment
- Personal protective equipment (PPE)
- Segregation
- Transport
- Cleaning processes and agents
- ♦ Disinfection (where required)
- Drying and inspection
- ♦ Sterilisation
- Packaging
- ♦ Storage
- Product release
- ♦ Testing of decontamination equipment
- ♦ Completion of test records/logbooks

## **Higher National Unit specification: Statement of standards (cont)**

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### **Evidence Requirements for this Unit**

Learners will need to provide evidence to demonstrate their knowledge and/or Skills across all Outcomes by showing that they can:

### Outcome 1

- Explain the importance of decontamination in:
  - Preventing the spread of infection
  - Ensuring staff and patient safety
- Describe the potential impact of non-compliance.
- ♦ Identify infectious agents capable of causing disease through inadequately decontaminated re-usable instruments.
- Describe the chain of infection including routes of transmission, routes of entry and methods to break the chain of infection.
- Explain the principles of decontamination and the different processes involved.
- ♦ Identify risk categories (Spaulding classification/Glennie) and determine appropriate methods of decontamination in relation to risk and contamination.

#### Outcome 2

- Define key stages in the decontamination of reusable instruments.
- Describe the purposes and differences between cleaning, disinfection and sterilisation.
- Identify the appropriate standard infection control precautions (SICPs) required to reduce the risk of injury, contamination and cross infection whilst undertaking decontamination eg hand hygiene, PPE, safe waste disposal, safe handling and disposal of sharps, environmental cleaning.
- List the correct course of action to be taken in the event of a sharps injury.
- ♦ Describe the operating principles of decontamination equipment (ultrasonic cleaners, washer disinfectors, Type N, B and S sterilisers).
- Describe the process of manual cleaning and assess when this would be required.
- Explain why automated methods of cleaning are preferred to manual methods.
- Explain the reasons for correct usage, loading and testing of decontamination equipment.
- Describe the periodic tests required for different types of decontamination equipment.
- Explain the importance of carrying out validation, testing and maintenance as part of manufacturer's instructions.
- Explain the importance of maintaining and completing documentation such as equipment log books, test results and training records.

## **Higher National Unit specification: Statement of standards (cont)**

**Unit title:** Local Decontamination of Re-usable Instruments

### Outcome 3

- Identify appropriate guidance documents relevant to local decontamination.
- Identify appropriate documentation for decontamination equipment and process records.
- Explain the potential impact of non-compliance with legislation, national guidance and local policy.
- Describe the principles and value of a Quality Management System in the management of decontamination.
- Describe key design considerations and requirements for local decontamination Units (LDU).
- Describe the management requirements for an LDU.
- ♦ Define the roles and responsibilities of key personnel in LDU as defined in SHTMs 2010 and 2030 in relation to decontamination in the work place.
- Explain the principles and content of an audit within the local decontamination Unit.
- ♦ Explain how to report any non-conformance with decontamination practices and potential non-compliance with Health and Safety legislation which could result in injury, infection or harm.
- Evaluate practice and suggest effective and safe measures to improve practice where necessary.

#### **Outcome 4**

- Safely collect used instruments for decontamination.
- Select and wear appropriate PPE.
- Sort used instruments and dispose of waste/single use items appropriately.
- Prepare reusable instruments for sterilisation.
- Identify how, when and what cleaning agents should be used for instrument cleaning.
- Prepare, load and operate decontamination equipment correctly.
- Carry out decontamination for successful product release.
- Ensure instruments are stored in a manner which prevents recontamination.
- Undertake daily and weekly periodic testing of decontamination equipment.
- Accurately complete test records and logbooks.
- Interpret test results provided to assess whether the decontamination equipment is safe and fit for use.



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Unit Support Notes are offered as guidance and are not mandatory.

While the exact time allocated to this Unit is at the discretion of the centre, the notional design length is 40 hours.

### Guidance on the content and context for this Unit

This Unit is an optional free-standing Unit within the framework of the HND in *Dental Nursing*. The content is expressed in generic terms in relation to the local decontamination of reusable instruments therefore the context can be adapted to suit different healthcare environments where local decontamination of instruments is undertaken, eg dentistry, podiatry and other relevant primary care settings.

The importance of decontamination in relation to preventing the spread of infection (**Outcome 1**) is emphasised and the Unit progresses to focus on the elements of decontamination and standards required for compliance in local decontamination (**Outcomes 2 and 3**). This can be delivered using classroom activities, practical exercises using common problems and scenarios when undertaking decontamination and group work. Candidates will also be expected to safely demonstrate how to process instruments according to these standards (**Outcome 4**) within simulated conditions.

Upon completion of the Unit candidates will be able to identify areas of good practise as well as any non-conformance with local decontamination standards within their workplace and make recommendations for improvement where appropriate.

The decontamination of re-usable instruments is a key element of infection prevention and control and safe working practice. This Unit has been designed to educate and inform learners regarding best practice that encompasses the decontamination of re-useable instruments. It provides underpinning technical and professional knowledge of the decontamination process, risks involved and standards required to ensure re-usable instruments are correctly and safely processed for the protection of staff and patients. It will also develop candidate's skills to allow them to evaluate the decontamination processes, facilities, equipment and management arrangements within their area of employment, identifying areas of good practice and taking action to improve practice where necessary.

It is suitable for individuals who undertake decontamination activities or have responsibility for decontamination activities within their workplace.

Decontamination is identified by the General Dental Council as being a core CPD subject for all dentists and dental care professionals.

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This Unit allows those with related healthcare qualifications such as the SVQ/PDA in *Dental Nursing* or the PDA in Oral Health Care: Dental Managers to build on their knowledge of decontamination. This includes the theory of the safe and practical application of decontamination in the workplace and identification of any required improvement(s).

## Guidance on approaches to delivery of this Unit

For Outcome 1, the importance of decontamination in relation to infection prevention and control and patient safety should be covered as well as the types of infectious agents capable of causing disease through inadequate decontamination, eg blood-borne viruses, vCJD, etc. Types of contamination which can affect instrument decontamination should also be explored.

The chain of infection is described to demonstrate how infections can be transmitted with methods given on how to break the transmission cycle.

Risk categories identifying the risk of vCJD associated with different types of procedures (Glennie) and the infection risk associated with different types of re-usable instruments and equipment and their usage (Spaulding) should be included with explanation of how decontamination methods depend on the type of material to be decontaminated, the type of contamination and micro-organisms involved.

Outcomes 2 and 3 can be delivered jointly as decontamination is a complex process. Success is dependent on a number of important factors being in place which are all interlinked, ie facilities, processes, equipment and quality management. The life-cycle of a re-usable instrument stretches from purchase to final disposal and includes key elements such as use, cleaning, disinfection, sterilisation, packaging, storage and transport. Health and Safety as well as good infection control practice relating to personal protection, safe sharps handling and effective hand hygiene is essential. Failure at any stage may result in inadequate decontamination and present a risk to staff or patient safety. Decontamination is also the subject of extensive regulation and guidance.

There may be opportunities to integrate delivery and assessment of these Outcomes with the Unit *Managing Quality in Dental Practice* FN3W 35, as audit is a requirement for this Unit.

Learners should therefore learn and be encouraged to examine their role in decontamination within their workplace, the legislative requirements and standards required for compliance and whether their practice (or the practice of others they are responsible for) is safe and in accordance with the standards. Candidates should be familiar with the requirements of compliance including the principles of audit and how to identify when remedial actions may be required to improve decontamination in their area. The following content requires to be delivered for these Outcomes:

### Legislation, Guidance and Relevant Agencies

Although the references to legislation and guidance given here are not exhaustive, they are intended to give a broad picture of the legal framework covering decontamination, the guidance available and the agencies involved.

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### **European Legislation and Regulations**

Medical Devices Directives (MDDs), eg MDD 93/42/EEC are transposed into UK law within the Consumer Protection Act as the Medical Devices Regulations. The Consumer Protection Act, in particular Product Liability, has implications for the reprocessing of devices used for patient care.

Other statutory controls related to instrument reprocessing include the Health and Safety at Act, the Control of Substances Hazardous to Health (COSHH) and the Reporting of Injuries, Disease and Dangerous Occurrences Regulations (RIDDOR). These confer a responsibility on to employers and employees to ensure safe systems of work which prevent the risk of injury or harm.

#### Standards and Guidance

Decontamination equipment must conform by law to British and European Standards which specify design, construction, performance and safety requirements.

Compliance with statutory regulations is an essential part of the decontamination process, as failure to ensure that reusable items have been reliably and effectively decontaminated could have potential legal, insurance and safety implications. As part of a comprehensive risk management and quality system, all stages of the decontamination process must be validated and tested.

Scottish Health Technical Memoranda (SHTM) have detailed information on how to choose, use, install and validate decontamination equipment:

- ♦ SHTM 2010 Sterilisation
- ♦ SHTM 2030 Washer disinfectors (including ultrasonic cleaners)
- ♦ SHTM 2031 Clean Steam

#### **Relevant Agencies**

The following are key regulatory and advisory bodies relating to the local decontamination in Scotland with associated websites:

Scottish Government Health and Social Care Directorate (SGHSCD)

The SGHSCD are responsible for the development of laws, formulation and implementation of policy and funding for matters affecting health and social care which includes decontamination. See www.scotland.gov.uk/About/People/Directorates

Health Facilities Scotland (HFS)

HFS is a division of NHS National Services Scotland and the HFS Decontamination Team leads the national decontamination agenda for reusable medical devices by standard setting, providing guidance and advice, audit, monitoring and support training programmes. HFS also provide validation authorising engineering services for decontamination equipment. See www.hfs.scot.nhs.uk/about/engineering-and-environment/decontamination-services

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Health Protection Scotland (HPS)

HPS is the principal organisation providing advice on health protection in Scotland including healthcare associated infections and infection prevention and control. See www.hps.scot.nhs.uk/haiic/decontamination/index.aspx

National Procurement

National Procurement are responsible for establishing and maintaining the NHS national contract for local decontamination Unit equipment. See www.nhsscotlandprocurement.scot.nhs.uk

Scottish Dental Clinical Effectiveness Programme (SDCEP)

SDCEP provides information on dentistry for the public and oral health professionals. The Scottish Dental website (**www.scottishdental.org**) has a decontamination section which provides links to various resources, advice and organisations that are relevant to decontamination in dental practices.

NHS Education for Scotland (NES)

NES develops and provides education for those who work in NHS Scotland. NES supports improvement in decontamination in dental practices through a variety of educational activities including continuing professional development courses, online learning modules and on-site training. Further information can be obtained through the NES Portal at www.portal.scot.nhs.uk

There is also an online decontamination education programme developed jointly by NES and HPS for staff working within a variety of primary care settings with modules on all aspects of decontamination within healthcare. The programme can be accessed at www.decontamination.scot.nhs.uk

#### **Facilities**

All decontamination activity is required to be undertaken in a location which is dedicated for the purpose and not shared with other activities. Scottish Health Planning Note (SHPN) 13 Part 2 — Decontamination Facilities: Local Decontamination provides guidance on the planning, design and operation of LDU facilities. Issues such as layout and design, workflow, segregation, operation, fixtures and fittings and equipment required in an LDU should be considered so that learner's can compare with their own decontamination facilities within their work environment.

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#### **Processes**

Decontamination is a combination of processes which includes cleaning, disinfection and sterilisation. The principles and elements of each of these methods should be explored with the learner in relation to:

- ♦ purpose
- factors influencing efficacy
- choice of automated versus manual cleaning
- choice of chemical versus thermal disinfection
- cleaning and disinfectant agents
- equipment required
- rinsing, drying, inspection of instruments
- ♦ storage
- processing complex items, eg handpieces
- health and safety and infection control, eg PPE, hand hygiene and safe handling of sharps

### Equipment

The choice of decontamination equipment available is vast. Successful decontamination cannot be validated retrospectively therefore must be validated before use, with the equipment used being routinely monitored, tested and maintained. The types of decontamination equipment available, eg vacuum versus non-vacuum sterilisers, how they work and how to choose the right equipment for your needs should be investigated. Procurement options, installation, operation, testing (to required parameters), maintenance and validation requirements should also be covered as well as packaging requirements.

### **Quality Management Systems**

A decontamination quality management system provides documented evidence that each stage of the decontamination process is being undertaken consistently and to the best possible standard. Learners should review the elements of a QMS which are particularly important, ie:

- standards, operational policies, procedures, protocols and guidelines in relation to decontamination
- documentation for each stage of the decontamination process, ie procedures, work instructions and records
- validation, maintenance and periodic testing records
- ♦ traceability
- staff training and training records
- kev personnel
- monitoring practice and records, eg by audit
- incident investigation
- reporting of non-conformance

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Procedures are required to identify any hazards associated with the decontamination process, estimate and evaluate the risk, control these risks, and monitor the effectiveness of any control measures. The absence of any of these elements may affect the quality of decontamination. Documented records are an essential component. These provide evidence that procedures have been followed satisfactorily and also provide a basis for audit.

### **Roles and Responsibilities of Key Personnel**

In relation to decontamination guidance, key personnel have been identified to ensure that decontamination procedures are safe, effective and implemented correctly. These include Management, User, Operator, Test Person (Sterilisers/Washer Disinfectors), Competent Person (Pressure Vessels), Maintenance Person (Sterilisers/Washer Disinfectors), Microbiologist (Decontamination) and Authorising Engineer (Decontamination). The roles of these key personnel should be explored, with learners then being able to determine who in their own workplace would fulfil these duties.

Delivery of Outcome 4 should integrate the teaching and learning of Outcomes 1–3. Outcome 4 requires the candidate to actively and safely process instruments through the key stages of local decontamination, utilising the knowledge gained from Outcomes 1–3 to demonstrate their skills in successful and safe instrument processing.

## Guidance on approaches to assessment of this Unit

Evidence can be generated using different types of instruments of assessment. The following are suggestions only. There may be other methods that would be more suitable to learners.

Centres are reminded that prior verification of centre devised assessments would help to ensure that the national standard is being met. Where learners experience a range of assessment methods, this helps them to develop different skills that should be transferable to work or further and higher education.

#### Outcome 1

This could be assessed by candidate responses to a series of restricted response or multiple choice questions.

### Outcomes 2 and 3

These Outcomes can be assessed by the production of an evaluation report based on a Realistic Working Environment (RWE) in relation to the current standards in local decontamination. The evaluation should include recommendations for improvement where appropriate.

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To ensure all aspects of the Evidence Requirements are included the evaluation should cover:

- individual and team roles and responsibilities for decontamination within the workplace.
- facilities provided for local decontamination.
- equipment and processes used to safely and successfully decontaminate re-usable instruments.
- measures taken to ensure quality assurance of the decontamination process.

Recommendations for improvement, where appropriate, should be included and a workplace action plan produced.

This report can be produced in any appropriate format.

#### Outcome 4

This Outcome may be assessed by observation of practice, supported by an observation checklist, which may be undertaken in simulated conditions either within the candidates own workplace or in a realistic working environment. It is not suited to delivery by e-assessment because it requires learners to be observed during the assessment.

# **Opportunities for e-assessment**

E-assessment may be appropriate for some assessments in this Unit. By e-assessment we mean assessment which is supported by Information and Communication Technology (ICT), such as e-testing or the use of e-portfolios or social software. Centres which wish to use e-assessment must ensure that the national standard is applied to all learner evidence and that conditions of assessment as specified in the Evidence Requirements are met regardless of the mode of gathering evidence. The most up-to-date guidance on the use of e-assessment to support SQA's qualifications is available at www.sqa.org.uk/e-assessment

# Opportunities for developing Core and other essential skills

There is no automatic certification of Core Skills or Core Skill components in this Unit. However, there are opportunities to develop aspects of the following Core Skills:

Communication (Oral and Written)

Candidates may develop their oral *communication skills* as they will be required to discuss the contribution made by all members of team to decontamination activities within their workplace and clarify specific roles and responsibilities relating to decontamination as per current decontamination guidance.

They will also be required to communicate their findings and negotiate with their colleagues in relation to any improvements required in decontamination practises, behaviour change and when addressing any potential areas of non-compliance.

Candidates may develop their written *communication skills* when producing their evaluation report.

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Information and Communication Technology

These skills may be further developed when researching current standards and guidance for local decontamination activities. They may also be required to use Information Technology when communicating and submitting their written report to their assessor.

### Problem Solving

This Core Skill may be developed when the candidate identifies any barriers to or areas of non-conformance and is required to implement change(s) to ensure best practice is achieved.

#### Numeracy

Skills in *numeracy* could be developed when test records from decontamination equipment require to be analysed and recorded.

### Working with Others

Skills with *working with others* may be developed as candidates must communicate and liaise with other members of the team in their workplace to ensure best practice in local decontamination is achieved from instrument use, processing and re-use.

Broader transferrable skills such as management, behaviour change and practice improvement may also be developed through the production of the evaluation report, recommendations for change, if applicable, and action plan.

# **History of changes to Unit**

Version	Description of change	Date

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### **General information for learners**

### **Unit title:** Local Decontamination of Re-usable Instruments

This section will help you decide whether this is the Unit for you by explaining what the Unit is about, what you should know or be able to do before you start, what you will need to do during the Unit and opportunities for further learning and employment.

This Unit is designed to enable you to recognise the importance of the decontamination process and your role within local decontamination. It will allow you develop your knowledge and skills in all aspects relating to the decontamination of re-usable instruments whether you are responsible for carrying out decontamination processes in your workplace or have supervisory responsibility for decontamination activities.

Throughout this Unit, you will learn about the importance of decontamination in preventing the spread of infection through re-usable instruments, the elements of the decontamination life cycle, the requirements which should ensure instruments are processed safely and how to process instruments successfully. The risks relating to decontamination, non-conformance and practice improvement will also be explored.

Overall you will be expected to use the knowledge and skills from this Unit to compare the decontamination practices undertaken within your workplace against national guidance and make recommendations for improvement where appropriate to your own practice or to the practices of others.

Upon completion of this Unit you will be able to:

- Explain the importance of decontamination in preventing the spread of infection.
- Explain the principles and elements in the decontamination life cycle of re-usable instruments.
- Explain the requirements for compliance in relation to current local decontamination guidance.
- Process instruments successfully through the key stages of local decontamination.

Assessment of the Unit will be varied, but will include some evaluation, report writing and observation of your practice.

There are opportunities throughout the Unit to develop aspects of Core Skills in Communication (Oral and Written), Information and Communication Technology, Problem Solving, Numeracy and Working with Others.

Completion of the Unit will assist participants to meet GDC compulsory CPD requirements.