

Project Management

Advice on the provision of Local Decontamination Units (LDUs)







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Local Decontamination Units (LDUs) Construction Project Management

Introduction

This paper has been produced at the request of the NHSScotland Health Board representatives who form the HFS Decontamination Working Group (DWG). The contents are primarily intended to advise and inform those who are responsible for the delivery of accommodation known as Local Decontamination Units (LDUs) to allow the decontamination of reusable medical devices to take place.

Note: The formation of a compliant LDU should only be undertaken as a last resort and after having completed an 'option appraisal' which has fully considered single use or mixed instrument provision and the use of a CDU accredited to BS EN ISO 13485 Quality Management System. The design layout and physical requirements of an LDU must comply with the Scottish Health Planning Note (SHPN) 13 Part 2 in this regard.

Purpose

The aim of this document is to seek to increase awareness of the technical professional and contractual interaction that will be invoked when healthcare agencies engage with the construction industry with the intention of entering into formal agreements for the provision of professional advice and/or construction works. This should enable the works associated with the provision of compliant Local Decontamination Units (LDUs) to proceed in an efficient and effective manner.

In order to ascertain what support services are required, those responsible for the provision of LDUs should:

- ensure that all persons involved have read and have a copy of SHPN 13 Part 2:
- identify the key elements of Project Management associated with the provision of new build or refurbished accommodation from project inception to completion and Hand-Over. See Appendix 2;
- identify the procedures required to comply with statutory and mandatory legislation and regulations associated with Local Authority, Health & Safety Executive, and NHSScotland in regard to construction projects and decontamination:
- identify options related to the Client Project Management Duties for the selection, briefing, appointing, induction and control of Professional Construction Consultants and Contractors;
- define the roles and responsibilities of the designated post holders who will perform the duties of Authorising Engineer (Decontamination) AE(D).

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Note: What is key to the delivery of the issues highlighted by the five bullet points, is a robust user requirement brief, an operational policy, and validated equipment throughput data, based on the anticipated instrument volumes.

The scope of the control procedures will also relate to the supply and installation of washer-disinfectors, sterilizers and other process equipment where these are to be installed as part of a 'several works package'.

The Chief Dental Officer Scotland has recommended to the dental service providers that equipment in NHSScotland LDUs should be sourced from the National Framework – ref NP143/09 which lists validated equipment. Equipment not on the Framework should not be installed. Equipment installation and commissioning should be by the Framework supplier. There is a requirement for a maintenance contract and for quarterly and annual testing, all of which are available from the Framework.

Overview

Given the variable range of technical support that exists across NHSScotland, it is evident that External Consultants will have to be employed in some regions to assist with the project management tasks, if the delivery of the improvements required are to be completed within a reasonable time framework.

NHSScotland Boards and Employed Agents who are contracted to work for NHSScotland Boards should make use of the guidance contained within this production.

Note: Individuals tasked with the responsibility for delivery of the facilities described as LDUs are required to understand where there are legal duties to fulfil as well as demonstrating good practice.

Activities programme

In order to amplify the stages of work from project inception to works completion, the activities involved have been broadly grouped into four stages.

Stage 1 – Site surveys

Initial Surveys may have already taken place to establish and collate basic project information, such as named contacts, locations, addresses and a broad description of the type, size and style of accommodation identified. For example, if the property is owned or leased, if the property is isolated or part of a terrace or tenement development.

Stage 2 – Operational plan

Review data from site surveys and determine if projects can be managed and delivered:

- in-house:
- by use of external consultants;



a combination of both.

Once this has been established an action plan should be developed to ensure projects are managed and delivered by the most suitable method.

By interrogating the data which has been collated on a site by site basis, it should become evident to an experienced professional where a Building Warrant is likely to be required from the Local Authority Department of Planning and Building Control. Typical examples will be when the works envisaged will involve changes to the building structure, windows and doors, or the electrical or mechanical services and water and drainage systems. The high water temperature discharge from Washer-Disinfectors typically 80-90°C will probably also require notification to the appropriate authority – Scottish Water.

Some Local Authorities also require that the water/drainage provider's Compliance Officer is also to be notified. Contact details can be found on the local Council website.

Similarly, where any of the works involve external additions or alterations, or where internal re-planning envisages a 'change of use' within existing compartments, or where the consequences of the alterations or changes are likely to impact on 'adjoining proprietors', the 'local community', or 'development plan', 'conservation area status' etc. then Planning Permission is likely to be required.

Note: Building Warrant and Planning Approval can take several months following approval of the scheme design by the Local Authority.

If the duration of the works is likely to exceed thirty days, or involves more than 500 person days inclusive of equipment installation, then the Construction (Design and Management) Regulations 2007 (CDM) will be invoked requiring formal notification to be made to the local Health & Safety Executive (HSE). The notification form (F10) is available from H.S.E. www.hse.gov.uk/forms/notification/f10.pdf

Note: The Local Authority and HSE should always be consulted for advice in regard to the correct procedures **before** contracts are placed.

Definitions of each of the terms used in the following section together with a description within the glossary are attached as Appendix 1 to this paper.

Stage 3 - Project delivery vehicle

The aim of the project delivery vehicle is to select, brief, fee negotiate or tender, appoint, and manage Design Consultants and Contractors to ensure that a proper and robust management methodology is in place for the provision of the LDU facility.

There is also a Client legal duty to appoint a CDM Co-ordinator who will have specific and prescribed duties in regard to the regulations – for example by providing competency checks of the selected consultant and or contractor and





for creating the pre-tender **Health and Safety Plan** for submission to HSE together with provision of the Health and Safety File on project completion.

Unless 'major' new build or refurbishment is envisaged, a Building Surveyor may be the most cost effective route for carrying out the role of Lead Consultant or Contract Administrator. This agent can then be employed to provide any of the necessary formal applications to the Local Authority and also to assist with:

- option appraisals;
- selection of contractors;
- preparation of scheme design;
- issue of tender documentation;
- cost control procedures:
- project manage the works to completion.

The terms and conditions of the contracts between the NHSScotland Board or other employer and the consultant and building contractor need to be agreed and a formal appointment made in writing by the employer (client).

Sample 'Forms of Contract' and 'Letters of Appointment' can be found on Health Facilities Scotland website; www.hfs.scot.nhs.uk/publications Pro-code Vetting and Control of Contractors.

Stage 4 - Contract Completion and Hand-Over.

This important stage of the completion process involves several formal procedures to be concluded and recorded before acceptance of the facility. The CDM Regulations in particular require that the Health and Safety File be provided to the Client/User before the facility is brought into use. The Health and Safety File will be compiled by the CDM Co-ordinator and Principal **Contractor**. Staged payments to Building Contractors and Equipment Suppliers are usually released only on production of a 'Certificate' denoting that a specific stage has been reached within the terms of the contract.

Warranties and Defects Liability Periods will usually commence from the date of issue of the Certificate of Practical Completion. A defects list, or snagging list is usually produced and issued to the Principal Contractor at the time of Hand-Over by the Contracts Administrator.

A Certificate of Making Good Defects together with a Final Certificate is also usually issued at the end of the Defects Liability Period by the Contracts Administrator and this production again triggers actions for release of Retention Monies by the Client.



Note: It is essential that due care and consideration is given within the project programme to enable proper co-ordination of all aspects associated with the commissioning of building services plant and equipment. The validation of decontamination equipment in particular is a formal process involving specialist attendance by the equipment installation agents and the Appointed Authorising Engineer Decontamination AE(D)

The items listed below are typical of the kind of documentation that should be available to assess suitability or otherwise of Hand-Over.

Hand-over documentation	Issued by
Certificate of Practical Completion	Contracts Administrator (Building Surveyor)
Test Certificates - Building Services, Mechanical and Electrical and Fire Alarm System.	Principal Contractor
Outstanding Defects - Snagging list	Building Surveyor
Building Warrant - Completion Certificate	Local Authority
Planning Approval - Consent	Local Authority
Test Certificates Equipment + Validation	Manufacturer and independent validation service such as HFS.
Health and Safety File:- Also incorporating the Client User Design Brief requirements and design drawings.	CDM Co-ordinator – Principal Contractor
As-fitted documentation and list detailing names and address of contractors and subcontractor and suppliers together with web site references and CD-ROM of component data and maintenance schedules.	Client and Building Surveyor/Contractor Suppliers.
Register of Client, Design Team, CDM Co- ordinator and Contractor Appointment letter etc.	All relevant parties

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Note: This list is compiled as 'Typical' documentation produced and should not be taken in part or in full as being applicable to each and every form of contract or agreement between the parties. The client, together with the Contracts Administrator and the CDM Co-ordinator should consult and agree and list the documentation that should be incorporated within the 'as fitted' and Health & Safety file. Good practice dictates that dust control methodology as described in SHFN 30: Infection Control in the Built Environment http://www.hfs.scot.nhs.uk/publications/shfn-30-v3.pdf and HAI-SCRIBE http://www.hfs.scot.nhs.uk/publications/hai-scribeimplementation-strategy.pdf both published by Health Facilities Scotland (HFS): should be evaluated and the outcome should be recorded as part of the overall hand-over documentation. The AE(D) should be appointed to collate, review and compile the documentation and certification relative to installed equipment. The person with the management responsibility for ensuring the quality and contents of the 'Safety File' should be 'Named' within the contract documents and letters of appointment.



Appendix 1: Glossary

Project Delivery Vehicle

The combined application of people, policies, procedures and guidance notes in a structured methodology deemed appropriate by the Client and suitable for the process required for the provision of LDUs.

Select

This term is used to describe the process of evaluating the suitability of an individual, company, organisation, supplier etc. to meet a given 'standards' criterion. Examples of criteria include

- competence;
- experience;
- resources:
- qualifications;
- reputation etc.

When selecting an individual company or organisation etc, qualifications should be validated together with employer liability, professional indemnity insurance cover, membership of professional institutions and trade associations.

A company structure which recognises Health and Safety responsibility within its policies and procedures in regard to management of risk should be demonstrated. Awareness and commitment to environmental management should also be evident within company policy and procedures.

Brief

This process is used by the client to ensure that consultants and contractors are adequately and properly informed of the duties, quality standards, restrictions, programme timescales, and other deliverables that will influence the resources required to fulfill the obligations imposed within the contract conditions.

 Briefing methods can be verbal or written but should always be recorded as a formal record of transfer of information between the parties. The CDM Coordinator must be advised of risks that are known to exist within the accommodation or as a likely consequence of executing the works.

Tender

A tender is the formal process of obtaining competitive bids for executing the works or supply of goods and services, required within the terms and conditions provided by the client.



Appoint

The formal process of acceptance of a formal bid or offer.

For a contract to be in place this must be done in writing through the exchange of contract documents between the parties. It is much more appropriate to use a 'standard form' of appointment for consultants and to always use a standard form of contract when appointing a works contractor. The placement of a formal 'order' may be acceptable to contractors and suppliers where the contract conditions allow.

Note: Some appointments must be made in writing to prescribed legal standards. For example to be in compliance with CDM Regulations the appointment of the CDM Co-ordinator and Principal Contractor.

Train

Within the context of this document, training should be taken as meaning the provision of documentation, workshops, seminars, site induction etc, to impart knowledge and increase awareness of key elements associated with the provision of LDU compliant accommodation.

The Client should have a formal Briefing Meeting arranged after the 'acceptance' procedures have been completed. As part of this process (induction) the Client should consider if more specialist and targeted training should be provided for contractors, consultants, and installers for example in regard to Health and Safety and infection control. Specialist advice should be obtained from suitably qualified agents and or organisations – such as the Local Health Board Infection Control Advisors.

Manage

- a regular system of control measures or procedure in regard to progress, quality standards, and disruption factors, cost checks, payments, material deliveries etc. to ensure that the contract conditions are complied with. This usually is achieved via site meetings with formal certificates and instructions being issued by the supervising officer. The Client or the Appointed Agent -Project Manager or Surveyor convenes the meetings and issues minutes, requests for information sheets (RFIs) monitors health and safety performance against the 'safety plan', reviews method statements and risk assessments:
- to ensure construction contracts are properly managed a formal procedure is usually needed in regard to the issue of certificates and acceptances or hand-over from the contractor to the client body;
- those managing LDU delivery should ensure that Healthcare Fire Officers, Safety Officers and infection Control Practitioners are made aware of the works and will be engaged in the monitoring process. Infection Control Practitioners should be consulted early in the planning stages;
- Construction (Design and Management) Regulations 2007 and SHTM 00: Best Practice guidance for healthcare engineering

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<u>www.hfs.scot.nhs.uk/online-services/publications/engineering/</u> are some of the statutory and mandatory governance standards that apply to the design and management of building and engineering projects.

The undernoted are key elements that form part of the management regulations protocols and regimes.

CDM co-ordinator/Designer	Principal Contractor
Health & Safety Plan	
Health & Safety File	Authorising Engineer.
	A list of registered Authorising Engineers
	(Decontamination) is available through
	Institute of Healthcare Engineering and Estate
	Management (IHEEM) office@iheem.org.uk
	phone 02392823186

Several works package

a contract for the provision of accommodation associated with LDUs where
the Principal Contractor also assumes responsibility for the delivery,
installation and first stage commissioning of the water, electrical, drainage
and extract services associated with the provision of washer disinfectors,
sterilizers and other non moveable equipment. The equipment ordering and
payment process would normally be controlled directly by the Client.

Lead Consultant/Contract Administrator

The person named within the contract documents as having the responsibility for fulfilling the designated duties within the terms of the contract between the Client – The Health Board or Dental Practitioner - and the Building Works or Specialist Contractor.

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Appendix 2

Note: This form is intended for use by the person responsible for the overall delivery of the completed facility. It should be viewed as a live document being continuously updated to reflect the current project status. A separate sheet should be used for each location.

Progress record

Projects Manager

CDM Co-ordinator

r regress reserv	•						
Project Status							
Site Location Address	S						
Option appraisal com	pleted	Yes		No			
Conversion	Relocation					Do Nothing	
Planning permission	- Applied for	Yes		No		Not Required	
Building Warrant	- Applied for	Yes		No		Not Required	
Health & Safety F10	- Submission	Yes		No		Not Required	
HAI Scribe Survey	- Completed	Yes		No			
Contract Works	- Designed	Yes		No			
	- Tendered	Yes		No			
Management C	ontractor an	d Cor	nmiss	sioni	na Ta	am -	

Building Surveyor			
M & E Engineer			
Contractor			
Equipment Supplier			
Installation Company			
Other Contractors/Suppliers			
Service Authorising Engineer Decontamination AE(D)			

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Completion programme

Date of:-				
Tender returns	- Anticipated			
Works completion	- Anticipated			
Equipment installation	n - Anticipated			
Equipment testing	- Anticipated			
Microbiology testing	- Anticipated			
Commissioning	- Anticipated			
Facility hand-over				
Certification				
Completed by				
Job Title				
Doto				