Decontamination Relating to the Refurbishment of Pharmaceutical Facilities

Presented By:

John R Broomfield

9 November 2005

The Austin Company

The Austin Company

I MECH E

Decontamination Related to the Refurbishment of Pharmaceutical Facilities

- **Building History**

- **Operational Sources**
  Chemical contamination
  Microbiological contamination
  Radioactive contamination
  Contamination of soil
  Contamination of ground water

- **Constructional Sources**
  Asbestos containing materials
  Lead Paint

Building History

It is important to establish the full history of the facility being refurbished. This may not be the first refurbishment or change of use for the building and previous uses may have left a legacy of contamination which will need to be addressed.

It is not sufficient to assume that previous refurbishment works will have already dealt with any potential legacy contamination issues.

Ground contamination or other types of operational or constructional contamination may not have been disturbed during the last change of use but may become an issue during the current refurbishment.

Building History

It may well be the case that current legislation now regards previously acceptable substances as hazardous.

For example, MDF has been used by many manufacturers as the core for laboratory furniture items but it is being used much less nowadays as there is an increasing belief that the dust caused by drilling and cutting MDF could cause health issues.

MDF also uses formaldehyde resins in its manufacture and emissions from unfinished boards can give rise to concerns as formaldehyde is classified in the UK and Europe as a Category 3 Carcinogen.

Many European countries now place very stringent limits on the levels of Formaldehyde emission from MDF.

Building History

In the case of Asbestos the "Control of Asbestos at Work Regulations 2002" now places a Duty to Manage Asbestos Containing Materials on the building owner / occupier.

An Asbestos Register identifying the location and type of Asbestos Containing Materials within the facility should be available for inspection but this does not exclude the need for further survey work prior to any refurbishment as structured surveys are now a regulatory requirement.

An worthy consideration is to:

"Expect the Unexpected" when dealing with the potential for contamination.

Chemical Contamination

The potential for chemical contamination in Pharmaceutical Facilities is high due to the nature of work conducted within them.

It is highly recommended that a Hazop study be undertaken to assess whether contamination exists within an area and the levels that may be present.

This will establish if any action is required whether it be a simple general clean or if there is the need for further investigation and the possible employment of a specialist decontamination company.

Chemical Contamination

There are many areas where contamination may occur such as:

Fume cupboards, safety cabinets and extraction hoods including the associated extract ductwork and fans.

Laminar downflow booths.
Some older units may have been “built in” and the masonry construction may also have been contaminated.
Filters would require special attention

Laboratory benches and work surfaces, particularly where any protective coating has been worn away or breached.

Chemical Contamination

Drainage pipework both above and below ground.

Above ceiling voids. Dust and debris can collect over time and present a possible hazard.

Within utility service casings and ducts either from dust or possible leakages.

Process areas including any redundant process equipment which may be scrapped as part of the demolition works.

Drum or bulk storage areas which may have suffered spillages.

Chemical Contamination

Where the equipment is accessible, hoods and cupboards can be physically Deep Cleaned by using Alcohol based wash downs and other forms of neutralising agents.

If the contamination is considered too difficult to neutralise or remove then the units may have to be disassembled, bagged or contained in an appropriate manner and then sent for disposal to a registered disposal site.

The work of disassembling would need to be carried out using the appropriate protection and this could include PPE ranging from masks to full air suits. It may be necessary to seal off the area whilst the work is being carried out and to clean down the area once the work has finished before allowing any other activities to take place.

Chemical Contamination

The extract ductwork can often pose a more difficult problem.

Access to the ductworks interior may be difficult to achieve and depending on the materials of construction it may not be possible to clean off or neutralise the contamination.

In these instances removal of the contaminated material may be the only option.

Fixatives may also be considered to reduce the shedding of contamination during disassembly.

Chemical Contamination

Expect the Unexpected –

One example is where Percloric Acid had been used within a fume cupboard for many years.

Even though the extract ductwork had an internal wash down facility there was the possibility that some of the joints within the ductwork had retained small amounts of Perclorate which in its crystalline state can become explosive when subject to friction or impact.

This was further complicated by the evidence of a leak from the ductwork at some point in its history making the brickwork surrounding the extract ductwork subject to the same potential contamination.

Chemical Contamination

The resultant action from the Hazop was to employ the Atomic Energy Authority to attend the site complete with armoured vehicles and operatives in explosion proof suits to very carefully dismantle the brickwork, ductwork and fume cupboard and to remove it all for safe disposal.

Much to everyone's relief - and some peoples slight disappointment – not a single pop or bang was experienced.

Chemical Contamination

Laboratory Benching can be cleaned or neutralised as above but where contamination has become ingrained in the fabric of the furniture then disassembly and disposal may be the best procedure.

Drainage pipework can often be flushed or treated before being removed or having new connections made to it.

Care should also be taken when the facility has a history of use involving pyrophoric catalysts e.g. Palladium on activated carbon.
When wet these pose no apparent problem but when dry they can spontaneously ignite. Build ups in drains can be problematical.

Chemical Contamination

Concealed spaces or ceiling voids can prove difficult as the action of gaining access to the contaminated space will itself expose operatives to the contamination.

Depending on the level of contamination this may be possible using PPE but in more heavily contaminated areas there is likely to be a need for screening off of the area concerned and the provision of air suits for the operatives working inside the area.

Chemical Contamination

In the case of redundant equipment it would be normal to expect a Clients users to ensure that any redundant equipment has been cleaned prior to being left for disposal but unless a certificate has been issued confirming that this is the case caution should be used.

Spillages within drum or bulk storage areas may well affect the slab and soil beneath. It may be possible to resolve this by encapsulation of the contaminated area but is more likely to require removal of the affected structure and often the soil beneath it and this can be a costly and time consuming exercise.

Microbiological Contamination

As with chemical contamination the possibility for microbiological contamination in Pharmaceutical Facilities is also high.

Once again it is highly recommended that a Hazop study be undertaken to assess whether contamination exists within an area and the levels that may be present.

The areas where contamination may occur are similar to those for chemical contamination but would be treated in a different manner.

Microbiological Contamination

The most likely form of decontamination would be fumigation or sterilisation. This can be achieved by the use of fumigation agents such as Formaldehyde or Hydrogen Peroxide.

It can also be achieved by sanitisation or disinfection using liquid agents to perform wash downs or in which to soak smaller contaminated items.

Moist heat is another example of decontamination which can be effective in some cases of microbiological contamination.

Radioactive Contamination

The use of isotopes in both laboratory and production situations can potentially lead to low grade radioactive contamination.

Radioactive decontamination is a specialist activity and is beyond the scope of this brief presentation other than to acknowledge that it may be required and that specialist advise should be sought.

Soil or Ground Water Contamination

In the event of ground contamination it is often the case that removal of the soil to the depth of the contamination is the only option. This can be very costly and disruptive, especially if the contamination extends beyond the boundaries of the required area of refurbishment.

Ground water contamination is an area which requires specialist advice. Instances such as high levels of solvents within static ground water have necessitated the steaming off of the solvents from the ground water. This is a solution that can take many weeks or months until acceptable levels are achieved.

Asbestos

The most obvious of the constructional contamination materials is surely Asbestos.

The identification and removal of Asbestos Containing Materials (ACM's) has become an Industry in itself with many regulatory and Health & Safety requirements governing its activities such as the Control of Asbestos at Work Regulations 2002.

Asbestos

As mentioned earlier each building should have an Asbestos Register identifying the location and type of any ACM's. This register would usually have been formed based on surveys such as those described in the Health & Safety document MDHS 100 – Surveying, sampling and assessment of asbestos-containing materials.

This would normally consist of a Type 1 (presumptive) survey which would identify the location, extent and condition of any ACM's within the building.

In some instances a Type 2 (sampling) survey may have been carried out at this stage particularly if some refurbishment work had already been carried out within the facility.

Asbestos

Prior to any refurbishment work taking place a Type 3 (pre-demolition/major refurbishment) survey should almost certainly be undertaken.

This survey work should be only be carried out by trained operatives who are fully aware of the Control of Asbestos at Work Regulations (and all of its amendments) and who operate within the requirements of these regulations.

Any actual removal of ACM's should only be carried by Companies who are licensed under the Asbestos (Licensing) Regulations 1983 and its amendments and all removal activities must be notified to the HSE at least two weeks prior to commencement of works.

Asbestos

Should you suspect that asbestos containing materials are present at any stage of a refurbishment, it is important not to disturb the material but to have an analysis carried out before any further action is taken.

ACM's can occur in a wide variety of places such as internal baffles on fume cupboards, gaskets in pipework systems, ceiling tiles, roofing sheets, floor tiles, insulation materials, etc the list is vast.

The best advise is that if you come across a material where you are not 100% certain that the material in question is NOT an ACM then have the material analysed before removal.

Asbestos

Expect the Unexpected –

One example is where some floor tiles were suspected of having asbestos content and were sent for analysis.

The result of the analysis was that the floor tiles were clear of asbestos but surprisingly the adhesive used to secure the tiles had an asbestos content.

The removal of the tiles was straight forward enough but the removal of the adhesive from the floor slab needed to be carried out without creating dust which eventually lead to the use of a solution which turned the adhesive into a slurry which was in turn scraped from the floor and disposed of.

Lead Paint

Instances of lead based paint are becoming less as time goes on but it is still a risk item.

There are no specific stipulations regarding how lead paint should be treated but any activity should follow the provisions of the Control of Lead at Work regulations 1998.

This includes the requirement for blood level monitoring of personnel exposed to any form of lead or lead based substances as lead poses a threat to health when it enters the blood stream.

As lead can enter the bloodstream through ingestion or inhalation any disturbance to the contaminated paint which would promote these mechanisms should be avoided.

Lead Paint

Whilst there is no mandatory requirement to remove existing lead based paint it is good advice to avoid disturbance of the painted surfaces and to label the substance with clear warnings as to its nature.

If practical then the correct removal and replacement of the paint should be considered so as to remove any potential risk.

Paperwork

The job isn't done until the paperwork is complete!

The correct disposal of any contaminated materials or waste must be closed out by the receipt of a suitably signed or certified disposal certificate.

This must be from a site licensed to accept and deal with the specific type of waste being disposed of.

For example there are only a few licensed sites where asbestos can be legally disposed of.

With asbestos waste it is essential for owners to obtain and keep certificates of disposal and to maintain a register of all disposal events.

The End

The Austin Company

The Austin Company