**TABLE 14.5** Minimum Laboratory Containment Standards for Working with Cells with Recombinant DNA

*Biosafety Level 1 (BL1)*

*A. Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
2. Work surfaces are decontaminated once a day and after any spill of viable material.
3. All contaminated liquid or solid wastes are decontaminated before disposal.
4. Mechanical pipetting devices are used; mouth pipetting is prohibited.
5. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.
6. Persons wash their hands after they handle materials involving organisms containing recombinant DNA molecules, and animals, and before leaving the laboratory.
7. All procedures are performed carefully to minimize the creation of aerosols.
8. It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.

*B. Special Practices*

1. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable,leakproof container that is closed before being removed from the laboratory.
2. An insect and rodent control program is in effect.

*C. Containment Equipment*

1. Special containment equipment is generally not required for manipulations of agents assigned to Biosafety Level 1.

*D. Laboratory Facilities*

1. The laboratory is designed so that it can be easily cleaned.
2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
3. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.
4. Each laboratory contains a sink for hand-washing.
5. If the laboratory has windows that open, they are fitted with fly screens.

In all cases, no viable organisms can be purposely released. Gas vented from the fermenter must be filtered and sterilized. All cells in the liquid effluent must be killed. The latter can present some operating issues, since the inactivation of the host cell must be done in such a way as not to harm what are often fragile products. Emergency plans and devices must be on hand to handle any accidental spill or loss of fluid in the fermentation area. These extra precautions increase manufacturing costs.

The issue of the regulation of cells and recombinant DNA will undoubtedly undergo further refinement with time. Both laboratory and manufacturing personnel need to keep abreast of any such changes.

## 14.8. METABOLIC ENGINEERING

Metabolic or pathway engineering uses the tools of genetic engineering to endow an organism to make a totally new pathway, amplify an existing pathway, disable an undesired pathway, or alter the regulation of a pathway. The principle motivations for metabolic engineering are the production of specialty chemicals (e.g., indigo, biotin, and amino acids), utilization of alternative substrates (e.g., pentose sugars from hemicellulose), or degrada-