Introduction:

National Institute of Health (NIH) has developed certain management procedures that can be adopted by research workers themselves to contain minor spills involving small quantities of biological materials/ experimental samples related to recombinant DNA. However, management of decontamination and cleanup of large spill or a spill involving a highly infectious agent are best left to the biosafety officer of the laboratory. It is the responsibility of the principal investigator to maintain an enough supply of a chemical disinfectant effective against the investigated microorganisms.

A spill may happen under various circumstances as below-

- in a biological safety cabinet,
- in the open laboratory,
- in a centrifuge,
- biological spill on a person and
- spill involving radioactive materials.

In each case, before starting the procedure and during the procedure, protective gloves, lab coat or gown, and eye protection should be worn. Researchers in the vicinity and the principal investigator should also be warned immediately. Decontamination with a recommended disinfectant procedure should be followed. Similarly, rDNA and transgenic organisms must be treated the same as medical or infectious waste before disposal. All wastes resulting from the procedure are to be disposed in the designated biowaste container.

Spill in a Biological Safety Cabinet:

A spill that is confined within a biological safety cabinet generally presents little or no hazard to personnel in the area. Chemical disinfection procedures are to be initiated at once while the cabinet continues to operate. The disinfectant should be active against the organisms of potential hazard.

i. Spray or wipe the walls, work surfaces, and equipment with the chosen disinfectant. Disinfectants with detergent have the advantage of detergent activity that will help clean the surfaces by removing both dirt and microorganisms.

ii. Minimize the generation of aerosols and use sufficient disinfectant to ensure that drain pans and catch basins below the work surface contain disinfectant. The front exhaust shall also be wiped and the disinfectant drained into a container.

iii. Lift the front exhaust grill and tray and wipe all surfaces. Wipe the catch basin and drain the disinfectant into a container.

This procedure will not disinfect the filters, fans, air ducts, and other interior parts of the cabinet. Contact bio safety officer if the interior cabinet needs to be disinfected.

Spill in the Open Laboratory:

For a spill in the open laboratory outside a biological safety cabinet, the spill response depends on the size of the spill and hazard of the material.

i. A minimally hazardous material spilled without generating appreciable aerosols can be cleaned with a paper towel soaked in a chemical disinfectant.

ii. A spill of a larger volume of hazardous material with aerosol generation requires evacuation of the room, waiting for aerosol reduction, donning personal protective gear (including appropriate respiratory protection), selecting a disinfectant effective against the organisms involved, and cleaning as described above. Following cleanup, responsible personnel shall wash or shower the infected area with a disinfectant soap.

iii. If clothing gets contaminated, it should be carefully removed and the contaminated area of the garment folded inward and kept for autoclaving.

iv. Wash arms, face, and hands with disinfectant.

Spill in a Centrifuge:

A biological spill in a centrifuge has the potential for producing large volumes of aerosols.

i. On becoming aware that a spill may have occurred within a centrifuge or other piece of equipment, turn off the equipment, allow aerosols to settle, and then decontaminate it.

ii. Place contaminated equipment in a leak proof bag and move it to a biological safety cabinet, if possible for decontamination.

Biological Spill on a Person:

If a biological material is spilled on a person, emergency response is based on the hazardous level of the biological agent spilled, the amount of material spilled, and whether significant aerosols were generated.

i. If aerosol formation is believed to have been associated with the spill, a contaminated person shall leave the contaminated area immediately. If possible, he/she should go to another laboratory area so that hallways and other public areas do not become contaminated.

ii. Contaminated clothes should be removed and placed in red or orange biohazard bags for disinfection.Contaminated skin shall be flushed with water followed by washing with a disinfectant soap. Showering can also be done, depending on the extent of the spill. A designated shower room should be earmarked near the laboratory.

Spill Involving Radioactive Materials:

Spills involving radioactive materials should be strictly handled by safety officer in charge. Following safety precautions should be taken under such situation:

i. Other laboratory personals should be warned immediately and if possible the place should be vacated.

ii. The principal investigator should be informed about the spill.

iii. The institute biosafety officer should be contacted immediately.

iv. One should not try to handle anything by himself.

Mechanism of Implementation of Biosafety Guidelines:

The guidelines suggest compliance of the safeguards through voluntary as well as regulatory approach. The implementation is enforced through the development of institutional frame work of advisory and regulatory bodies to deal with the specific and discretionary actions on the following:

i. Self regulation and control in the form of guidelines on recombinant research activities; and

ii. Regulation of large scale use of engineered organisms in production activity and release of organisms in environmental applications under statutory provisions.

The institutional mechanism as proposed for implementation of guidelines is shown in Figure.

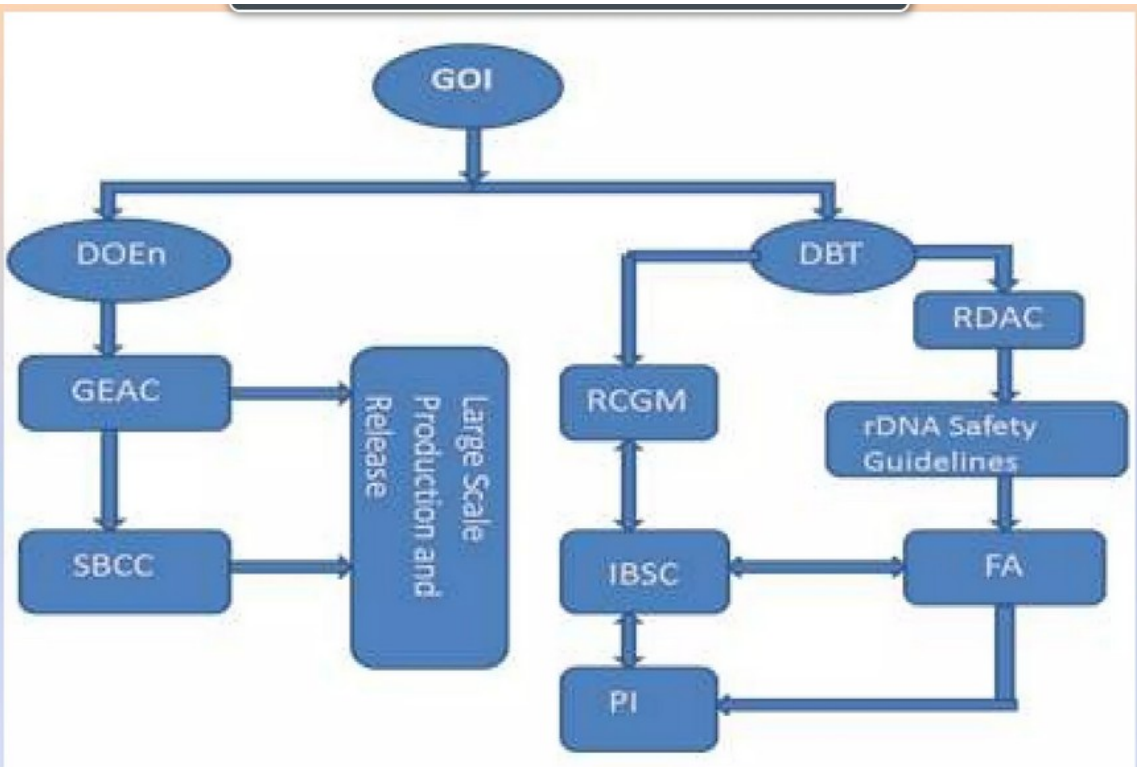
Mainly it consists of the following:-

i. Recombinant DNA Advisory Committee (RDAC)

ii. Institutional Biosafety Committee (IBSC)

iii. Review Committee on Genetic Manipulation (RCGM)

iv. Genetic Engineering Approval Committee (GEAC)



(**GOI**: Govt. of India, **DBT**: Department of Biotechnology; **RDAC**: Recombinant DNA Advisory Committee; **IBSC**: Institutional Biosafety Committee; **RCGM**: Review Committee on Genetic Manipulation; **DOEn**: Department of Environment; **GEAC**: Genetic Engineering Approval Committee; **SBCC**: State Biotechnology Coordination Committee; **PI**: Principle Investigator (R&D/Industry/Others); **FA**: Funding Agency (Govt./Private or Public Institution))

Recombinant DNA Advisory Committee (RDAC)

The Committee should take note of development and advances at national and international levels in Biotechnology towards the correctness of the safety regulation for India on recombinant research use and applications. The committee should be aware of recent developments and advances in safety regulation in recombinant research at both national and international levels. It should meet once in 6 months or sooner for this purpose.

The specific terms of reference for Recombinant Advisory Committee include the following:

i) To evolve long term policy for research and development in Recombinant DNA research.

ii) To formulate the safety guidelines for Recombinant DNA Research to be followed in India.

iii) To recommend type of training program for technicians and research fellows for making them adequately aware of hazards and risks involved in recombinant DNA research and methods for avoiding it.

Institutional Biosafety Committee (IBSC)

Institutional Biosafety Committee (IBSC) is to be constituted in all centres engaged in genetic engineering research and production activities. The Institutional Biosafety Committee shall be the nodal point for interaction within institution for implementation of the guidelines. Any research project which is likely to have biohazard potential (as envisaged by the guidelines) during the execution stage or which involve the production of either microorganisms or biologically active molecules that might cause bio-hazard should be notified to IBSC.

The biosafety functions and activity include the following:

i. Registration of Bio-safety Committee membership composition with RCGM and submission of reports: IBSC will provide half yearly report on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any. A computerized Central Registry for collation of periodic report on approved projects will be set up with RCGM to monitor compliance on safeguards as stipulated in the guidelines.

ii. Review and clearance of project proposals falling under restricted category that meets the requirements under the guidelines: IBSC should make efforts to issue clearance quickly on receiving the research proposals from investigators.

iii. Tailoring biosafety program to the level of risk assessment.

iv. Training of personnel on biosafety.

v. Instituting health monitoring program for laboratory personnel.

vi. Adopting emergency plans.

Review Committee on Genetic Manipulation (RCGM)

The RCGM will have the following functions:

i. To establish procedural guidance manual - for regulatory process involving genetically engineered organisms in research, production and applications related to environmental safety.

ii. To review the reports in all approved ongoing research projects involving high risk category and controlled field experiments and ensures that safeguards are maintained as per guidelines.

iii. To recommend the type of containment facility and the special containment conditions to be followed for experimental trials and for certain experiments.

iv. To advise customs authorities on import of biologically active material, genetically engineered substances or products and on excisable items to Central Revenue and Excise.

v. To assist Department of Industrial Development, Banks towards the clearance of applications in setting up industries based on genetically engineered organisms.

vi. To assist the Bureau of Indian Standards to evolve standards for biologics produced by recombinant DNA (rDNA) technology.

vii. To advise on intellectual property rights with respect to rDNA technology on patents.

Genetic Engineering Approval Committee (GEAC)

Genetic Engineering Approval Committee (GEAC) will function under the Department of Environment (DOEn) as statutory body for review and approval of activities involving large scale use of genetically engineered organisms and their products in research and development, industrial production, environmental release and field applications.

The functions include giving approval from environmental view on:

i. Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells including food stuffs and additives that contains products derived by Gene Therapy.

ii. Discharge of Genetically engineered/classified organisms/cells from Laboratory, hospitals and related areas into environment.

iii. Large scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. (Production shall not be commenced without approval).

iv. Deliberate release of genetically engineered organisms. The approval will be for a period of 4 years.

V. The funding agency will be responsible for approval and clearing of research proposals for grants in aid in respect of rDNA research activities.
VI. The funding agency at the centre and state level will be advised to ensure that the guidelines are taken into account for compliance while supporting grants on research projects.
VII. Investigators will be required to submit as part of the project application an evaluation of biohazards that may arise and also the requirement on the type of containment facility, certified by IBSC. The funding agency should state clearly that support on approved projects will be withdrawn in case of deliberate violation or avoidable negligence of the rDNA guidelines.
VIII. The investigators will also be asked to make a declaration in their publications that the work was carried out following the national guidelines.
IX. The funding agency will annually submit to RCGM the list of approved projects that come under high risk categories.