

### Purpose

The procedure is intended to ensure that all work with use of GMOs at NCMM is according to the Gene Technology Act and Regulations.

### Scope

The procedure applies to all contained use of GMOs and all research with such organisms. The procedure applies to all areas approved for contained use of GMOs

### Responsibility

*The Centre Manager* has overall responsibility to ensure that all contained use of GMOs at NCMM is going on in facilities approved by the Directorate of Health. Likewise that use and research is according to applications, notifications and approvals. Centre Manager must ensure that information about the procedure is communicated to all staff and students.

*The Group leader* must ensure that the areas for research with contained use of GMOs, is approved by the Directorate of Health in advance and that all contained use is according to applications, notifications and approvals. Instructions for the area shall contain information on the contained use of GMO, the use should be risk assessed, protective measures must be described and preparedness for adverse events / emissions specified. The group leader must inform all employees about the procedure in the relevant laboratory and ensure that it is understood.

*The User* is responsible for complying with this procedure and thus ensuring that the use is according to regulations. All contained use of GMOs should be risk assessed, control measures should be described in writing. All adverse events or releases of GMO material must be reported according to the procedure.

All laboratories approved for contained use of GMOs must be labeled in accordance to the rules for contained biosafety level with biohazard sign and the GMO / GMM in use.

### Approach

#### Approval of laboratories, notification and application for contained use of GMOs

<https://helsedirektoratet.no/genteknologi>

1. Laboratories / areas intended for work with the contained use of GMOs must be approved in advance by the Directorate of Health. The application for approval is submitted by the

Centre Manager at NCMM. Applications should be submitted on the standard form.

2. Research with the contained use of GMOs should be notified and approved by the Directorate of Health. Notifications/ applications on standard form are submitted by the Group leader.

### **Archive**

All applications, notifications and approvals are sent in cc to the HSE-coordinator/ administration to be archived in e-phorte.

### **Laboratory instructions and risk assessment**

The Group leader must ensure that the laboratory instructions for contained use of GMOs is risk assessed according to the biosafety level, and decide contained measures for protection and measures for adverse advents. This is to ensure proper implementation of the experiment, and that the use is within the approval for use of GMO given by the Directorate of Health.

### **Training and monitoring**

Group leader or laboratory manager must ensure that new users are familiar with and have understood routines and work with the contained use of GMOs. After training, the user must sign that training is provided and understood.

### **Adverse events – handling accidents and spill – notify**

#### **Procedure**

<http://www.med.uio.no/ncmm/english/about/hse/labwork/gmo/accidents-spills/>

### **Internal control - safety inspections**

The internal control system at NCMM, based on elaborate instructions with risk assessment and measures for all authorized GMO laboratories, make an overall routine for emergency and accidents handling GMO-work at the center. At the annual safety inspections at NCMM the group leader or laboratory manager must present the laboratory instruction with risk assessment for the GMO work taking place in the approved laboratory

### Definitions

*Genetically modified organisms (GMOs):* microorganisms, plants and animals whose genetic composition is modified by means of gene or cell technology.

*Microorganisms:* cellular or non-cellular microbiological unit capable of replication or of transferring genetic material.

*Cell Technology:* Techniques for the production of living cells with novel combinations of genetic material by the fusion of two or more cells.

*Genetic engineering:* techniques that involve genetic isolation, characterization, modified and inserted into living cells or viruses.

*GMM:* genetically modified microorganisms.