A Plausible Model for Monitoring Compliance with Containment Guidelines

There is a need to determine whether a particular laboratory engaged in or beginning recombinant DNA research has the appropriate containment capability for a given type of experiment. Insofar as possible this review process should not lengthen the time required for review of research proposals. The following model is designed for the grant review process and laboratories in universities or research centers in the United States. Quite possibly, with certain modifications, it could be adapted to the corresponding institutions in other countries.

Each university or research institution would have a biological safety office whose responsibility would be to assess or grade the physical containment facilities of its laboratories (e.g., assigning a rating of low, moderate or high risk containment according to established guidelines). This local office would provide the laboratory head with a statement certifying the physical containment rating of the laboratory; this rating would, of course, be subject to periodic reevaluation.

When an investigator applies to an agency for funds to support work on recombinant DNA molecules, the statement certifying the physical containment rating would be appended to the grant proposal. The group reviewing the research proposal would determine whether the certified level of physical containment was adequate for the

real or potential biohazard associated with the proposed experiments. Entering into the assessment of adequacy would be the type of DNA to be cloned, the scale of the proposed bacterial cultures to be used and most importantly the adequacy of the biologic barriers to be employed. If the reviewing group concludes that the experimental design and physical containment rating is commensurate with their and the investigator's estimate of the risk, the grant would be processed for scientific merit in the usual fashion. If there is some question of the adequacy of the containment capability, the experimental design or the investigator's estimate of the risks, the matter would be referred to an appropriate body (e.g., the NIH Advisory Committee on Recombinant DNA Molecules or its designate) for an opinion or ruling.

This proposed procedure would apply to new or renewal grant applications but it would clearly miss investigations supported by continuing grant support or by agencies not using such a monitoring mechanism. Nevertheless, it is likely that most investigators, because of self interest and a sense of responsibility to their colleagues, coworkers and other laboratory personnel, would comply with the same guidelines.