

PERMITTING, THE PUBLIC AND THE FUTURE OF ANIMAL BIOSAFETY FACILITIES

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ABSTRACT

Biocontainment facilities for animals are complex structures which must comply with numerous, sometimes conflicting, federal, state and local regulations. Agencies responsible for funding the construction of or permitting of such facilities must address the environmental impacts of the operation including the treatment and disposal of regulated medical waste.

Our experience illustrates the complex nature of the biocontainment facility permitting process. Furthermore, these experiences have taught us to seek public input early in the planning process and incorporate the public's concerns during the environmental quality review process. Finally, the recent decision in New York to regulate ABSL-3 facilities as regulated medical waste treatment facilities has added significant new requirements and resulted in a cost escalation that threatens the entire project.

INTRODUCTION

The two laws I will be discussing today deal with regulated medical waste (RMW) and environmental protection. Each state has developed laws and regulations to deal with these concerns; they vary somewhat in specific detail between states.

In New York State (NYS), RMW is governed by two agencies—The Department of Health (DOH) and the Department of Environmental Conservation (DEC). DOH sets the definitions, approves treatment technologies and regulates human health care centers and clinical laboratories. The DEC regulates storage, treatment and destruction of RMW on-site in non-health care facilities and the transport, storage and treatment of RMW off-site. Animal carcasses, body parts or bedding known to be contaminated with agents infectious to humans must be

treated as RMW. In NYS large RMW generators (>50 lbs/month) can treat on-site by using an approved DOH technology and, after submitting an Operating Plan, gaining approval from the DEC. Small quantity generators need only use an approved technology, no DEC approval or Operating Plan is necessary.

The College of Veterinary Medicine at Cornell University was considered a large quantity generator and operated a pathological incinerator under approval by the DEC since 1985. Conventional RMW (plastics, sharps) is shipped for off-site treatment by a certified RMW hauler.

When facilities receive untreated RMW from off-site sources to be treated at their facility, they become regulated by the DEC. First they must apply for a Part 360 Solid Waste Permit for treatment of RMW. This application must address each item listed in Table 1. Next the permitting agency must decide if the proposed "action" will have a significant environmental impact (to be discussed later). The permitting agency reviews and approves, disapprove or requires changes in any of the plans proposed by the facility. Once the institution is approved to construct the facility, it must demonstrate that all treatment technologies destroy infectious agents using the worst case scenario for validation. When the facility has a license to operate, it is bound to the conditions of the permit i.e. challenge testing each treatment technology after every 40 hours of service, quarterly reports to the DEC, maintenance of records for three years or the life of the facility. This can be extremely expensive and involve additional full-time personnel.

New York (and all other states) also requires every state and local agency to conduct an environmental review before making any discretionary decisions. Agencies include all local boards, authorities, districts, commissions, and governing bodies. A

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TABLE 1
Components of an Application for a Part 360 Permit to Construct and Operate a Regulated Medical Waste Treatment Facility

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| 1. Engineering Report | 8. Maintenance and Monitoring Plan |
| 2. Engineering Plans and Specifications | 9. Personnel Staffing and Training Plan |
| 3. Treatment, Destruction and Disposal Facility | 10. Waste Control Plan |
| 4. Validation Testing Program | 11. Contingency Plan |
| 5. Surety | 12. Closure and Financial Assurance Plans |
| 6. Facility Plans | 13. Security Plan |
| 7. Operation Plans | |

discretionary decision includes funding or approving a privately or publicly sponsored action, or to directly undertake an action. The review procedure is designed to help agencies, sponsors of projects and the public to protect the environment and the process is called the State Environmental Quality Review (SEQR).

If the State University Construction Fund decides to fund construction of a building on one of its campuses or to build it themselves, they must first conduct a SEQR (because these are direct actions of an agency). If Cornell decides to apply for a Part 360 Solid Waste permit to accept off-site regulated medical waste, the DEC must conduct a SEQR before making the discretionary decision to issue a permit.

The SEQR process begins by deciding whether the proposed action is exempt or excluded or if the activities fall under the category of type II actions (those known as never having a significant impact on the environment i.e. replacing a facility, in kind, on the same site). If the action is not exempted or type II, the agency must prepare an environmental

assessment form (EAF) which is shared with all involved agencies for their comments. If after review of the EAF and comments the agency decides there is no aspect of the action which will be environmentally significant, they may make a Negative Declaration and the SEQR process stops. If a significant impact is envisioned, the agency provides a Positive Declaration which requires an Environmental Impact Statement (EIS) to be submitted (see Figure 1).

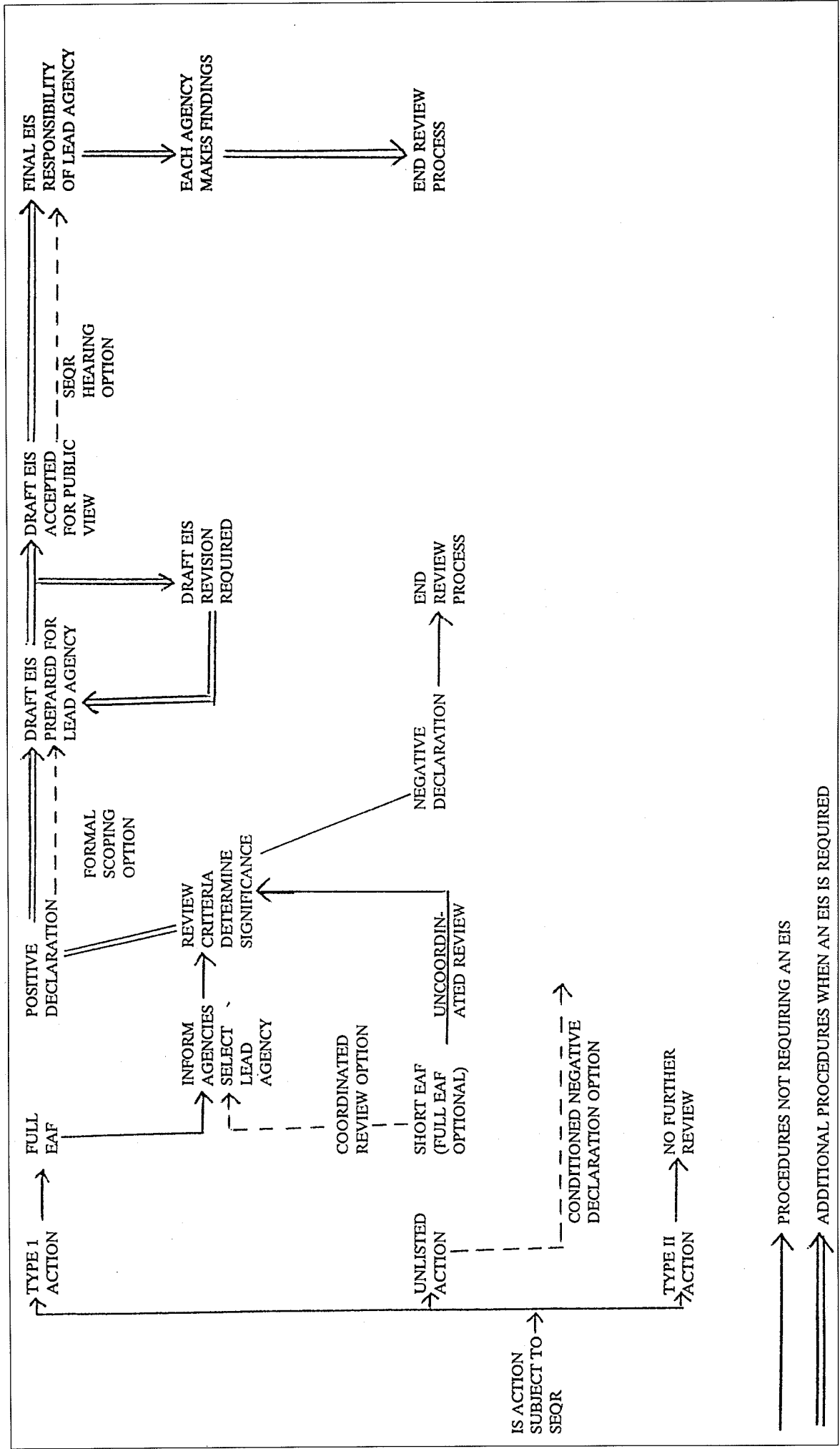
The EIS process begins when the applicant (or agency if they propose a direct action) prepares a draft EIS. This DEIS relates any environmental considerations to the inception of the planning process, informs the public and other agencies of proposed actions that may impact the environment and solicits comments which will assist in agency decision making. Table 2 lists the components of an EIS. After a sufficient period for public comments (i.e. at least 30 days) a final EIS is prepared which incorporates all mitigation measures designed to reduce environmental impacts. Upon completion and review the lead agency and all other involved agen-

TABLE 2
Components of an Environmental Impact Statement

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|---|---|
| 1. Description of the proposed action and its environmental setting | 6. Mitigation measures proposed to minimize environmental impacts |
| 2. Environmental Impact of the proposed action | 7. Growth-inducing aspects of the action |
| 3. Adverse environmental effects which cannot be avoided | 8. Effects of the action on the use and conservation of energy resources |
| 4. Alternatives to the proposed action | 9. Effects of the proposed action on Solid Waste Management |
| 5. Irreversible and irretrievable commitment of resources | 10. Effects on the comprehensive management plan for special groundwater protection |

FIGURE 1

The SEQR Process



cies must prepare their findings and file them together with the lead agency's decision to fund or approve an action. The intention of this process is to identify and mitigate potential negative impacts on the environment before an action (like building construction) is initiated. This process takes a minimum of six months and may take considerably longer (Figure 2). With this as background, let me share with you Cornell's most recent experience.

As previously mentioned, Cornell has an incinerator which is used to destroy RMW animal carcasses and infected bedding. In addition, all euthanized laboratory animals or their remains and animal carcasses from diagnostic cases (where there is a suspicion of infectious disease) are incinerated. This incinerator was constructed before the implementation of the SEQR review and was exempt from review.

In the 1980s we began planning two new animal biosafety level 3 facilities (ABSL-3); one for small laboratory animals and the other for domestic livestock. The State University Construction Fund (SUCF) decided to fund both structures and initiated the SEQR process for both. After review of the Environmental Assessment Form, the SUCF, with input from the DEC, made a Negative Declaration for each facility. There were no challenges to this decision and construction was initiated on both.

In 1992 the SUCF decided to replace the Veterinary College incinerator with a new incinerator, equipped with full EPA air emission controls, to treat conventional RMW along with carcasses. Again the SEQR process, which included a meeting between Cornell and the town zoning board, led to a negative declaration. As air and solid waste permit applications for this new incinerator were being prepared, the public became aware of the college's intention to incinerate RMW plastics and immediately formed both student and non-student associations opposed to the incinerator. Letters were sent to various agencies, calls, letters, e-mails were sent to the Dean and various other officials at the university, posters were circulated and finally one group threatened to contact all alumni in an effort to apply additional outside pressure.

In 1996 the Dean held a public meeting to explain the state's prior SEQR decision and review plans for the proposed facility. The public's response was predictable. Within a month the Dean

shelved the permit applications and called for the formation of the Cornell Community Waste Management Advisory Committee (CCWMAC) (although it took nearly six months to agree upon that name). This committee was composed of 22 members representing local government agencies, student groups, community associations who had an interest in the proposed incinerator plus several members representing college and university administration and faculty. This group has met faithfully since August of 1996 with the Community Dispute Resolution Center personnel acting as facilitators. Implicit from the beginning was the Dean's request that this group advise him (and the college) on the best program to manage regulated medical waste.

During the past year, eight working groups were established to: develop a library and hire educators for the committee, develop criteria which must be met by the final program, investigate all technologies useful for treatment of RMW, communicate with local and state officials to clarify issues pertaining to permits, survey the waste stream, investigate and report on waste minimization, hire environmental and engineering consultants, and liaison with these consultants. The learning curve was very steep for a long time as all members were educated about toxicology, risk assessment, and various treatment technologies. Despite failure to come to closure after two self-imposed deadlines, the committee is working diligently with outside consultants and a final recommendation is expected by June 1998.

In February 1997, the NYS DEC made effective a new ruling that facilities that work with BSL-3 or BSL-4 agents must have all treatment technologies approved through the Part 360 Solid Waste Permitting Process for RMW. This, I believe, is a requirement unique to New York. With two ABSL-3 facilities at 90% completion we were required to submit Part 360 applications. Naturally this initiated the SEQR review. While we still have not heard whether the original Negative Declarations will be honored or not, it is likely that an EIS will be requested. Consultants have been hired to assist Cornell in preparing the Part 360 application.

In November 1997 the DEC reversed its previous decision and reclassified the college's existing incinerator. Because animals were brought to Cor-

FIGURE 2
SEQR Time Frames

FILE NOTICE of all Positive Declarations and all Conditioned and Type 1 Negative Declarations		FILE NOTICE of Completion of Draft EIS and SEQR Hearings		FILE NOTICE of Completion of Final EIS							
Propose Action Submit Part 1 EAF	30 days (maximum)	20 days (maximum)	60 days (maximum)	No time frame	45 days	15 days (minimum) 60 days (maximum)	No Time Frame	45 days (maximum)	10 days (minimum)	Variable	FINAL AGENCY DECISION
	Establish Lead Agency	Determine Significance	Scoping (Optional)	Prepare DEIS	Determine Completeness Adequacy of DEIS		1 hearing	Prepare FEIS		Findings by Each Agency	
Public Comment Period											

nell for disease diagnosis and necropsy from off-site and because historically some of those animal harbored human infectious agents, we are now listed as a RMW treatment facility accepting RMW from off-site. This now requires a Part 360 permit which must be filed no later than April 1, 1998 and it will initiate the SEQR process. A consultant has been hired to assist us in filing this permit.

As of today we have two ABSL-3 facilities nearly ready for operation, but closed awaiting Part 360 permits to cover waste water treatment, manure sterilization, an alkaline hydrolysis tissue digester and three autoclaves. We have an existing incinerator operating under special agreement until April 1, 1998 at which time a Part 360 permit must be submitted. We are unable to replace this incinerator with any other final treatment technology until the CCWMAC makes it's final recommendation. After they make their recommendation a Part 360 permit application must be prepared for the incinerator replacement.

Conventional regulated medical waste continues to be treated off-site at considerable expense to the college. The CCWMAC's activities have cost the college over \$300,000 and the Part 360 application consultants cost approximately \$100,000. These expenses are not being paid by a State Agency and are funded primarily through unfilled faculty positions. We are also poised for up to four EISs to cover each of the aforementioned projects. In the past EIS documentation and meetings have cost \$150,000 per project.

What have we learned from this?

Regulatory agencies can initiate new rulemaking or modify previous decisions in ways that can pro-

foundly affect a university's operations. When this happens the state agency originally responsible for construction funding may not be responsible for funding additional permits.

While we are among the first of NYS institutions to comply with the new Part 360 application for ABSL-3 facilities, others must comply soon and in all likelihood this requirement will be mandated in other states.

CONCLUSION

As a public institution it is probably prudent to involve the public on each major undertaking from the earliest planning stages. This early involvement will elucidate areas of public concern and prepare the institution to address those concerns. In retrospect the college should have insisted on an EIS for the new incinerator even if the lead agency gave it a Negative Declaration. The time, financial and adverse public relations consequences arising from our previous decisions may have been avoided had we involved the public during planning for all aspects of our biosafety animal facilities programs.

FURTHER READING

- New York State Department of Health. Managing Regulated Medical Waste. DOH, December, 1995.
- New York State. State Environmental Quality Review. (Environmental Conservation Law) Sections 3-0301 (1)(b), 3-0301 (2)(m) and 8-0113. 6 NYCRR Part 617.
- New York State Dept. Environmental Conservation. Environmental Conservation Law, Article 8-Environmental Quality Review. DEC, July 1992.
- New York State Dept. Environmental Conservation. Regulated Medical Waste Treatment Facilities. 6NYCRR Subpart 360-17.