Final Report

Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States

Submitted to:

American Society for Microbiology
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Washington, DC 20036
and
National Institute of Allergy and Infectious Diseases
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Submitted by:

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June 2, 2005

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June 2, 2005

Ms. Janet Shoemaker
Director, Public Affairs Office
American Society for Microbiology
1752 N Street, NW
Washington, DC 20036

RE: NIH/NIAID/American Society for Microbiology (ASM) Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States

Dear Ms. Shoemaker:

Constella Group, LLC, is pleased to submit this final report of findings from the recently completed Survey of facilities with BSL-3 capability in the United States.

We have appreciated the opportunity to develop and administer this important survey to provide NIAID with the information needed to assess location, capacity, and status of current BSL-3 facilities.

If there are any questions concerning this submission, please contact me at 919-313-7585. We have enjoyed working with you and Ms. Hedetniemi and others from NIAID and look forward to working with you again in the future.

Sincerely,

Edward E. Gaunt, Ph.D.
Project Manager

Cc: Janyce N. Hedetniemi, NIAID Community Relations Advisor

TABLE OF CONTENTS

LIST OF EXHIBITS

LIST OF APPENDICES

1 EXECUTIVE SUMMARY

The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), in partnership with the American Society for Microbiology (ASM) signed a letter of agreement with Constella Health Sciences of Atlanta, GA, in October 2004 to develop and conduct a brief survey of academic, biotechnology, and pharmaceutical facilities in the United States (US). The purpose of the survey was to provide NIAID with information that would help better define the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment. BSL-3 containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Environmental Health and Safety Officers (or an equivalent individual) working at academic, biotechnology, and pharmaceutical facilities were mailed a survey solicitation to encourage their participation and to provide them with the necessary information to logon to a secure survey website and complete the survey. The survey instrument provided a set of qualification criteria to help the respondent determine if any laboratories within the respondent's facility met the minimal requirements for BSL-3 containment as described. Respondents whose facilities included BSL-3 capable laboratories were then asked to complete the five remaining survey questions. These questions addressed the number and size of the BSL-3 capable laboratories, the current type(s) of work being conducted in the laboratories, and their research capabilities. Survey recipients in facilities that did not have BSL-3 capable laboratories were not required to complete the remainder of the survey.

Due to the sensitive nature of the requested data, a secure online submission form was developed to protect the integrity of the responses and respondents. To protect the data, the Secure Sockets Layer (SSL) protocol was used to encrypt communications between the client machines and the web server. In addition, all survey recipients were informed that their submitted responses are exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), as provided in the Department of Health and Human Services (DHHS) regulations implementing the FOIA.

Although it was expected that the Census Survey would include nearly all facilities with BSL-3 capable laboratories, it was possible that there were BSL-3 capable facilities that were not captured in the Census Survey population. Therefore, in accordance with the Office of Management and Budget's (OMB) request, a Validation Survey was conducted to evaluate the comprehensiveness of the population of facilities identified for the Census Survey. A random sample of microbiologists from the membership list of the ASM was developed and used for the Validation Survey.

Throughout the survey administration period, submissions, response rates, and respondent inquiries and questions were tracked, monitored, and verified on a daily basis. At 20 days and again at 30 days after the initial mailing of the Census Survey, facilities that had not yet responded were mailed reminder postcards. Survey solicitations returned by the US Postal Service (USPS), for any of several reasons, were followed by telephone or e-mail to obtain the correct address or name of the most appropriate addressee. The survey solicitation was then remailed to the facility.

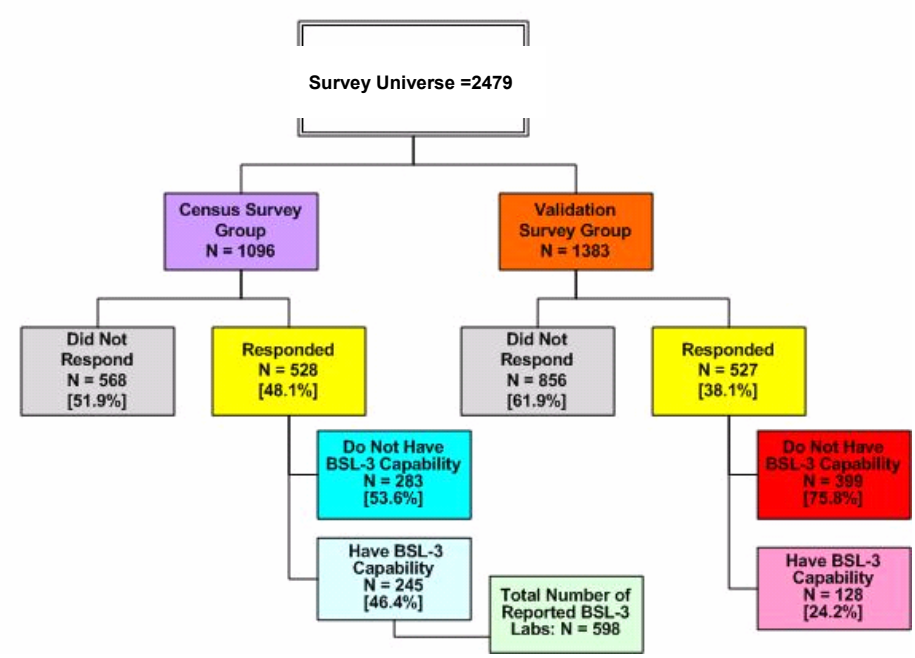
A survey assistance e-mail address (LabSurveyHelp@asmusa.com) was established and maintained throughout the data collection period so that survey recipients could post questions or comments while completing the survey. The same e-mail address was provided for both the Census and Validation surveys and was provided in the solicitation letter, the response postcards, the reminder postcards (Census Survey only), and listed on the survey website. Inquiries sent to this e-mail address were monitored daily and responded to within 24 hours of receipt.

The OMB-approved termination date for actively soliciting information from survey recipients was February 28, 2005. No surveys were mailed after that date but responses were accepted until March 9, 2005. Survey responses submitted after March 9, 2005, were not included in the analyses of results.

Overall, 2170 surveys were distributed (see Exhibit 1 below). Of the 1096 facilities mailed a Census Survey, 48.1% (N=528) responded. Nearly half of the 528 responding facilities (245 or 46.4%) indicated that they currently have BSL-3 capable laboratories while 283 (53.6%) stated that they do not have laboratories with BSL-3 capabilities.

For the Validation Survey, 1383 individuals were mailed a survey solicitation letter. Of this group, 38.1% (N=527) responded. One hundred twenty eight (128) of the responding individuals (24.2%) indicated that the facility at which they are employed has BSL-3 capable laboratories and 399 (75.8%) indicated that their organization does not have BSL-3 capable laboratories.

Exhibit 1: Distribution of Survey Results: This diagram shows the distribution of both Census and Validation Survey results.



There were 1096 Census Surveys and 1383 Validation Surveys distributed in two separate surveys. However, 309 of the recipients received copies of both surveys. Of the 309 facilities that were mailed both surveys, 204 (66%) responded, either to the Census Survey only, the Validation Survey only, or to *both* surveys. If a facility responded to both surveys, their responses were checked for agreement and any disparate results triggered a phone call to the facility in order to resolve the true BSL-3 capability of that location. The results from both surveys were then merged in such a manner that only one recorded response per facility was retained. In total, the surveys identified 277 distinct facilities, in 46 states, that currently have BSL-3 capable laboratories.

2 BACKGROUND

The most critical roadblock to developing biodefense countermeasures is the lack of specialized research resources, in particular, specialized biocontainment laboratories. This need was identified in 2002 when the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), convened a Blue Ribbon panel of experts to help define the Institute's research agenda for Category A agents[1]. The Panel identified a "serious shortage of high containment laboratories in which to perform experiments using dangerous pathogens." NIAID's strategic plan for biodefense research includes a long-range strategy to support construction of the required biocontainment research facilities. In Fiscal Year 2003, NIAID provided funding for construction of two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). These new facilities will complement and support NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research and other NIAID research activities. The biocontainment laboratories will be available and prepared to assist national, state and local public health efforts in the event of a bioterrorism or infectious disease emergency.

In 2004, the NIAID recognized a need to further refine information about current BSL-3 laboratory capacity in the US. In partnership with American Society of Microbiologist (ASM), NIAID conducted a survey of academic, biotechnology, and pharmaceutical facilities in the US to help better identify the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment. BSL-3 containment is applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

The collaboration between NIAID and ASM was an essential part of the BSL-3 laboratory survey. ASM is the oldest and largest single life science society in the world and is composed of over 40,000 members involved in education, research, public health and clinical microbiology. The stature of ASM and its reputation as the premier organization for the biomedical research community conveyed an important message to survey respondents about the importance of the survey and the professionalism with which the project would be handled. The survey was developed by NIAID and ASM and was approved by the Office of Management and Budget (OMB) on September 30, 2004 (OMB No. 0925-0537, expiring February 2005). Constella Health Sciences, under a letter of agreement with ASM, provided technical support and direction for the conduct of the survey and data analyses. The survey is a one-time effort; there is no plan to maintain or update the information collected.

[1] Category A diseases/agents, as defined by the Centers for Disease Control and Prevention (CDC), are organisms that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness. Category A agents include anthrax, botulism, plague, smallpox, tularemia, and viral hemorrhagic fevers.

3 METHODS

To establish a base of understanding, both surveys began with a qualification question that asked the respondent if any laboratory within the facility meets the described minimal containment criteria for BSL-3 laboratories[2] as listed below:

1. Entry into the laboratory is by passage through a series of two self-closing doors (and the doors must be lockable).
2. The laboratory contains a Biological Safety Cabinet as defined in Appendix A of the fourth edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
3. Air from the laboratory is not recirculated, but is exhausted outside or through HEPA filters.
4. Air pressure in the laboratory is less than (negative to) the air pressure in the surrounding workspace (i.e., other laboratories or office/administration space).
5. All infectious waste generated in the laboratory is decontaminated before disposal off-site.

The survey recipients were asked to review the criteria above to determine if any laboratories within their facility met the described minimal requirements for BSL-3 containment. A link was provided to the Biosafety in Microbiological and Biomedical Laboratories (BMBL) criteria for BSL-3 labs. The five criteria presented above were considered as primary discriminators of a BSL-3 capable laboratory.

If the recipient's facility did not meet the criteria noted above, no response was required. Recipients who had BSL-3 capable laboratories within their facility were asked to complete the survey questions. For the Census Survey, there were five questions that sought to determine the number and size of the BSL-3 capable laboratories, the current type(s) of work being conducted in the laboratories, and their research capabilities. For the Validation Survey only two questions were asked: were there laboratories at the respondent's location that met the BSL-3 criteria above and if so, what was the Zip+4 of that location?

3.1 CENSUS SURVEY

The purpose of the Census Survey was to collect information from US academic, biotechnology, and pharmaceutical facilities on the status of existing and operating BSL-3 laboratories for use by the NIAID in planning for construction of new facilities.

The Census Survey consisted of a self-administered questionnaire to gather data about the types of facilities with BSL-3 capability as well as specific laboratory demographics (i.e., the number and size of BSL-3 laboratories at a specific zip code, types of work being conducted, and other capabilities). The recipients of the Census Survey were asked to complete the survey online but were given the option of responding via a paper survey if desired. (No survey respondent elected to submit a paper survey).

[2] See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm).

3.1.1 Census Survey Mailing List

The target population for the Census Survey represented a "best estimate" of the "universe" of facilities with BSL-3 capable laboratories in the US. The mailing list for the Census Survey included academic, commercial, and laboratory response network (LRN) laboratories. No Federal government laboratories were included in either the Census or the Validation Study. The survey solicitation was addressed to the individual at targeted facilities most likely to provide accurate and comprehensive data (typically the official who holds the title "Environmental Health and Safety Officer" or equivalent). The final mailing list for the Census Survey was derived from the following databases:

- **Universities**: US based universities, medical schools, and biomedical research institutions selected from the top 1,000 NIH grant-receiving facilities.
- **Biotechnology companies**: US constituency of the Biotechnology Industry Organization (http://www.bio.org) members.
- **Pharmaceutical companies**: US-based members of the Pharmaceutical Research and Manufacturers of America (PhRMA, http://www.phrma.org)
- **Laboratory Response Network**: A portion of the Centers for Disease Control and Prevention integrated network of laboratories that can respond to both bioterrorism and chemical terrorism events (http://www.bt.cdc.gov/lrn/). This list included 65 state and local public health laboratories that provide testing on clinical specimens to measure human exposure to biological and toxic agents.
- **Biosafty Listserv**: A solicitation notice was placed on the Biosafty Listserv (biosafty@mitvma.mit.edu, now operating under the auspices of the American Biological Safety Association at biosafety@biosafety.absa.org). This is a discussion listserv of approximately 700 biosafety professionals. An additional seven facilities were identified from this posting that had not previously received a Census Survey solicitation.
- **"Additional" laboratories**: Facilities that received the initial Census Survey were urged to provide the addresses of any additional BSL-3 capable facilities affiliated with their organization but located within a zip code other than the one to which the initial solicitation was mailed. Respondents were instructed to logon to the survey website and provide the additional address(es) and a contact person who could provide information regarding the BSL-3 laboratories at that location. Forty-four (44) additional facilities were identified in this manner.
- **Additional academic laboratories**: An additional 66 academic laboratories were identified from a supplementary listing of NIG Grant recipients obtained in early January 2005. This list was obtained because we felt that the initial December mailing under-represented academic laboratories in the Census Survey population.

All of the individual lists were compiled into one file and duplicate addresses were removed. The compiled mailing list was then sorted according to zip code (to facilitate bulk mailing) and each addressee was assigned a unique identification number and logon password. The combination of the above resources, after review for redundancy, identified 1096 facilities considered highly likely to have BSL-3 capable laboratories. All 1096 facilities were mailed a Census Survey solicitation.

3.1.2 Census Survey Instruments

Although the major component of the Census Survey was administered via the Internet, survey solicitation materials were mailed to the prospective respondents to inform them about the survey and to encourage participation. The following printed materials were mailed:

- **Cover letter**: A cover letter was developed in conjunction with NIAID and ASM that explained the goals of the survey and solicited the response and support of the recipient. The cover letter was signed by the President of ASM and printed on ASM letterhead. Cover letters were addressed to the officer at the institution most likely to be the appropriate survey respondent. If a specific individual could not be identified, the letter salutation was "Dear Environmental Health and Safety Officer" (see Appendix A1).
- **Instruction Sheet**: The survey instruction sheet contained information to assist the respondent in completing the online survey or in responding to the survey solicitation by returning the response postcard. The instruction sheet also provided the recipient with an email address if assistance was needed or if there were any questions or concerns (see Appendix A2).
- **Response Postcard**: Each recipient received a response postcard that served two functions. First, it listed the minimal criteria for determining whether any laboratory in their facility meets BSL-3 containment requirements. Second, the response postcard could be used to respond to the survey. If the recipient's facility did not have laboratories that met the minimal BSL-3 containment requirements, then a negative response could be marked (i.e., the facility does NOT have BSL-3 capabilities). The cards were then returned in the mail without the respondent having to logon to the survey website. The response postcard were preaddressed and pre-franked so that minimal effort was required to submit a response (see Appendix A3).
- **Paper Survey**: A paper alternative to online response was provided. If the recipient's facility did have BSL-3 capable laboratories but the recipient did not have internet access (or if the respondent preferred to not submit results online), the respondent could check the appropriate box on the response postcard and return it. They were then mailed a paper copy of the survey. No paper surveys were requested nor distributed.

3.2 VALIDATION SURVEY

The Validation Survey was designed to evaluate the comprehensiveness of the population of facilities identified for the Census Survey. The Validation Survey solicited information from a random sample of individual ASM members whose employers were not part of the Census Survey but who work at a facility that may have BSL-3 capable laboratories.

The Validation Survey was also available for online response or via completion and mailing of the response card included in the mailing.

3.2.1 Validation Survey Mailing List

The mailing list for the Validation Survey was compiled using a random sample of microbiologists from the membership list of ASM. The ASM membership list consists of approximately 43000 individuals. For purposes of the survey, all foreign members were eliminated. Of the remaining 25750 domestic members, 7000 members were excluded because their self-designated primary and secondary subject area disciplines did not include areas of

study that would require BSL-3 capabilities. The zip code (Zip+4) of the remaining population of ASM members was then compared with the Zip+4 of the population of facilities responding to the Census Survey. Any ASM member who was affiliated with a Census Survey facility was removed from the list. All addresses that subjectively appeared to be a home address were removed. From this remaining list, a random sample of 1500 members was drawn. Of the random sample of 1500, complete mailing address information was available for 1383 individuals, all of whom were mailed a Validation Survey solicitation.

3.2.2 Validation Survey Instruments

As with the Census Survey, the Validation Survey was designed primarily for completion online. Validation Survey candidates were sent materials similar to those described in Section 3.1.2 above: a cover letter explaining the purpose of the survey; an instruction sheet describing how to complete the survey; and a response postcard (see Appendices B1-B3).

The Validation Survey was a self-administered questionnaire consisting of two questions. The first question described the minimal requirements for BSL-3 containment as defined in Section 3 above. The respondent indicated whether or not any laboratories within his or her immediate facility met these qualifying criteria. If the respondent indicated that his or her work location had one or more laboratories with BSL-3 capability, they were asked to provide the nine-digit zip code (Zip+4) for that address. These responses could be provided online or via completing the pre-addressed and franked response postcard.

3.3 CONDUCT OF THE SURVEY

The Census Survey and the corroborating Validation Survey were conducted during the winter of 2004-2005. Survey responses were monitored on a daily basis and the survey status was provided to the survey administrative team during weekly updates.

3.3.1 Survey Distribution

Using the combined list of candidate facilities, the Census Survey solicitation was mailed to 984 initial recipients via the US Postal Service (USPS) on December 1, 2004. The solicitation packet included a cover letter, instruction sheets, and a response postcard. An additional 112 survey packets were mailed out to other recipients between December 1 and January 15, 2005, for a total of 1096 candidate facilities.

The Validation Survey was mailed via the USPS to 1383 ASM members on January 17, 2005. The Validation Survey packet included a cover letter, an instruction sheet, and the response postcard. Follow-up activities such as reminder postcards or additional letters were not conducted for the Validation Survey.

3.3.2 Data Collection

Each mailing contained a response postcard for recipients to complete and return. If no laboratories at the recipient's facility met the minimal containment criteria for BSL-3 laboratories, they indicated a negative response (i.e., the facility does NOT have BSL-3 capabilities) by checking the appropriate box on the card and returning it in the mail or by logging onto the Survey Website and providing their response.

If the recipient's facility did have BSL-3 capable laboratories, they had the option to log on to the secure survey website using the provided facility identification number and password to

complete the survey. For respondents at facilities with BSL-3 capable laboratories, but who did not have Internet access (or preferred to not submit results online), the respondent also had an option on the response postcard to request a paper copy of the survey. The response postcards were preaddressed and pre-franked so that minimal effort was required to submit a response. Although survey recipients were given the option to request a paper survey, no survey recipient exercised this option and no paper surveys were distributed.

3.3.3 Non-Respondent Follow-up

All Census Survey recipients who had not responded within 20 days of the initial mailing were sent a reminder postcard prompting them to go online to complete the survey. A second reminder postcard was sent approximately 30 days after the initial mailing. The initial response and each reminder postcard were printed on different colored, heavy cardstock in order to draw the survey recipients' attention and to be easily identified (see Appendices C1 and C2).

3.3.4 Final Plea Letter

Only Census Survey recipients were sent a final plea letter (see Appendix C3). The purpose of the final plea letter was to serve as a final reminder and to increase response rates. The letter was mailed to all non-respondents approximately 45 days after the initial survey solicitation was mailed.

Exhibit 2 provides a summary of the numbers and dates of each survey mailing.

Exhibit 2: Summary of the Type, Number Sent, and Dates of Each Mailing Administered During the Census and Validation Surveys

Type of Mailing – Census Survey	Number Sent	Date Sent
Initial Survey	984	Dec 1, 2004
Additional Academic Facilities	61	Jan 21, 2005
Biosafty Listserv	7	Upon receipt
"Additional" Laboratories	44	Upon receipt
Census Survey Follow up	**Number Sent**	**Date Sent**
First Reminder Postcard	984	Dec 20, 2004
Final Reminder Postcard	948	Dec 30, 2004
Final Plea Letter	783	Jan 13, 2005
Type of Mailing – Validation Survey	**Number Sent**	**Date Sent**
Validation Survey	1383	Jan 17, 2005

3.3.5 Assistance (E-mail Helpline)

An e-mail helpline was maintained throughout the data collection period to respond to any questions from survey recipients and survey participants. The email address was published in the cover letter, the response postcard, on each reminder postcard, and on the survey website. Exhibit 3 presents the type of questions or issues posed in the course of the survey.

Exhibit 3: Survey Recipient Requests for Assistance Sent to LabSurveyHelp@asmusa.org	
Questions Received	**n = 22**
"How do I add Additional Facilities?"	6
"Should I fill out both the Web survey and postcard?"	10
"What is the purpose of the survey?"	2
"Should I fill out survey if the lab is not at this site?"	4
Issues Received	**n = 25**
Macintosh computer not compatible with Web browser	3
Facility ID or Password did not work	2
The "Continue" button did not work	9
Recipient did not feel comfortable filling out survey	11

3.3.6 Survey Timeline

Exhibit 4 provides a timeline of events related to both the Census and Validation Surveys. OMB approval took 73 days from submission of the initial request to receipt of approval. The survey was distributed 27 days after the Letter of Agreement was completed with Constella Health Sciences and the survey was completed within 90 days of the first mailing

Exhibit 4: BSL-3 Laboratory Survey Timeline

Event	Date
Original OMB Request	Jul 19, 2004
Final OMB Approval	Oct 01, 2004
Constella Letter of Agreement Signed	Nov 04, 2004
Initial Survey Mailed	Dec 01, 2004
First Reminder Postcard Mailed	Dec 20, 2004
Final Reminder Postcard Mailed	Dec 30, 2004
Final Plea Letter Mailed	Jan 13, 2005
Validation Survey Mailed	Jan 17, 2005
Last Day to Solicit Responses	Feb 28, 2005
Census Survey Close Date	Mar 09, 2005

4 SURVEY RESULTS

In this section, analyses of responses to both surveys are provided to show the distribution of responses by mailing list as well as by facility type. A question-by-question response to the five survey questions that were asked of the Census Survey recipients is also provided.

4.1 SURVEY DISTRIBUTION AND RESPONSE

As discussed previously, a total of 2479 survey packets were distributed (1096 Census and 1383 Validation Surveys). The survey response for both surveys is shown in Exhibit 5. Of the respondents, 528 of 1096 (48.1%) of the Census Survey recipients completed the survey and 527 of 1383 (38.1%) of the Validation Survey recipients responded. This represents an overall response rate of 42.6% for the entire survey population.

Census Survey respondents declared that 46.4% of their facilities had BSL-3 capability, while 24.2% of the Validation Survey respondents declared the same.

Exhibit 5: Census and Validation Survey Responses

Response	Census Survey	Validation Survey
Number of Survey Packets Distributed	1096	1383
Number and % of Survey Respondents	528 (48.1%)	527 (38.1%)
Number and % of Respondents declaring BSL-3 Capability	245 (46.4%)	128 (24.2%)

Exhibit 6 shows the number of recipients from each mailing list, as well as the number (and percent) of respondents by list and finally the percentage of respondents who identified BSL-3 capability.

Exhibit 6: Distribution of Census Surveys and Survey Responses by Mailing List

Mailing List	Distribution N	Respondents N (% of distribution)	Respondents with BSL 3 Capability N (% of respondents)
NIH Grantees	457	329 (71.9%)	136 (41.3%)
BioIndustry	405	138 (34.1%)	11 (8.0%)
Laboratory Response Network	65	49 (75.4%)	48 (98.0%)
Additional NIH Academic Grantees	61	11 (18.0%)	0 (%)
PhRMA	57	34 (59.7%)	10 (29.4%)

Exhibit 6: Distribution of Census Surveys and Survey Responses by Mailing List			
Mailing List	Distribution N	Respondents N (% of distribution)	Respondents with BSL 3 Capability N (% of respondents)
Additional Labs (identified by other survey recipients)	44	38 (84.1%)	34 (89.5%)
Biosafety Listserve	7	7 (%)	6 (85.7%)
ASM Membership (Validation Survey)	1383	527 (38.1%)	128 (26.2%)

The mailing lists that yielded the best response rates were the Additional Labs (identified by other respondents) as well as the NIH Grantees and the LRN laboratories.

Only 18% of the additional NIH Grantee academic institutions receiving the January Census Survey mailing responded to the survey and none of these declared BSL-3 capability. This was anticipated because most of these institutions were smaller academic institutions not heavily invested in biological research.

Not all of the additional laboratories identified by other survey recipients declared BSL-3 capability, even though the Survey asked the respondent to identify other BSL-3 laboratories affiliated with their facility, but which were located on other campuses.

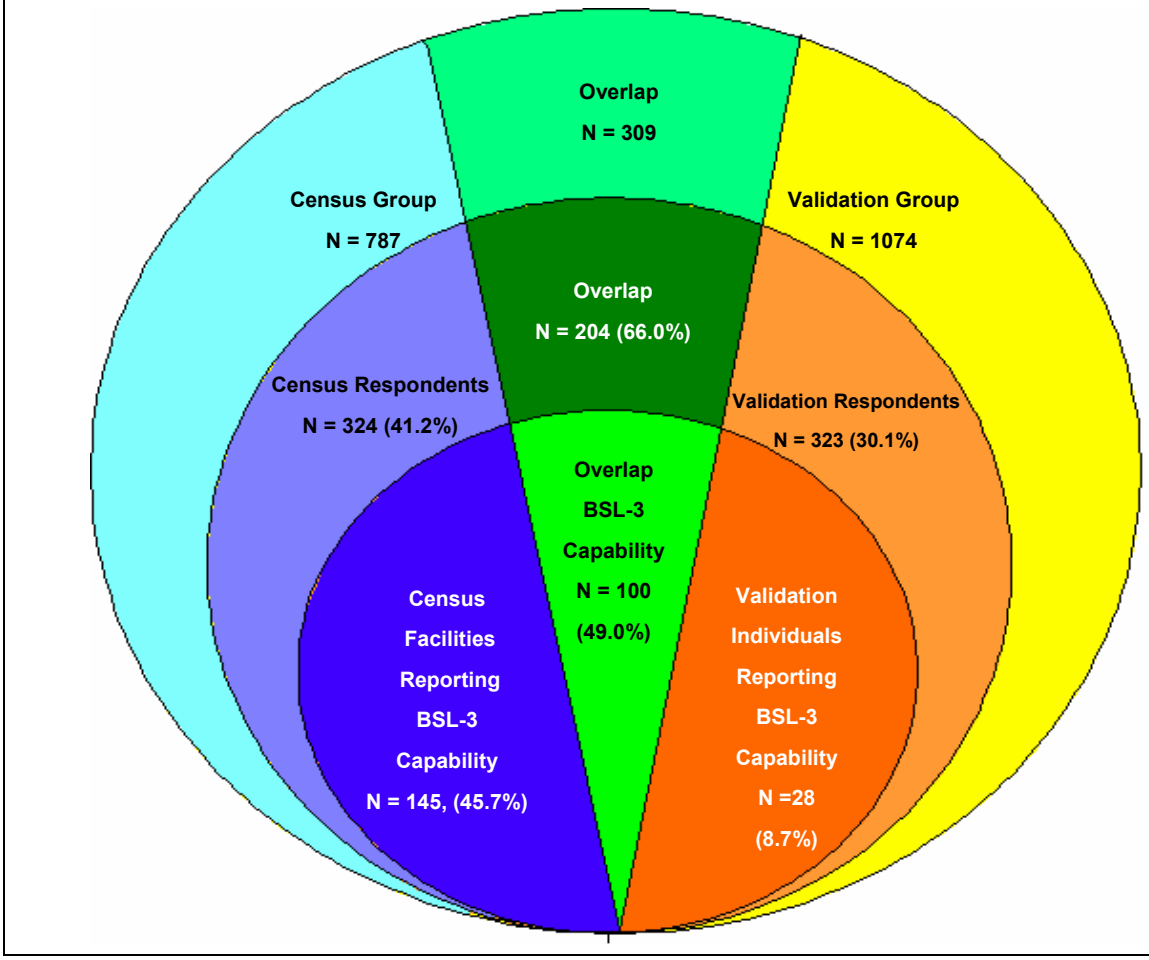
4.1.1 Combined Census and Validation Survey Responses

As discussed in Section 3, a total of 1096 survey packets were distributed to Census Survey recipients (see Section 3.1.1) and 1383 were distributed to Validation Survey recipients (see Section 3.2.1. Thus, a total of 2479 survey packets were distributed. However, upon further analyses of the respondents' addresses (e.g., comparison of Zip+4) or facility names, a total of 309 of these facilities received both Census and Validation Surveys (entities in this group were dubbed "overlap" recipients). This occurred because the Validation Survey was distributed to individuals who were ASM members, and some of these members worked for facilities that had also received the Census Survey mailing. Thus, there were 2170 distinct entities that received surveys.

Exhibit 5 above provides data with reference to the 1056 survey responses; 528 from the Census Survey group and 527 from the Validation Survey group. However, 204 of these respondents were from the "overlap" group described above. In those instances when both a Census and Validation Survey were received from a facility with the same Zip+4 address or facility name, the responses were verified to determine if both were in agreement (that is they both indicated that the either did or did not have BSL-3 capabilities). In those few occasions where the results were not in agreement (N=9), the facility was contacted by telephone to determine the true response.

Exhibit 7 shows the relationship between Census and Validation Survey respondents by illustrating the overlap where respondents received both a Census Survey and a Validation Survey.

Exhibit 7: Relationship Between Census and Validation Survey Respondents



4.1.2 Geographic Distribution of Survey Responses

The following exhibits show the aggregated state-by-state geographic distribution of survey responses for both the Census Survey and Validation Survey.

Exhibit 8 shows the geographic distribution of Census Survey facilities that have BSL-3 capability. Eight states (CA, WA, WI, PA, NY, CT, TN, and FL) are reported to have nine or more BSL-3 capable laboratories, while Texas is reported to have between seven and eight facilities.

Exhibit 8: Geographic Distribution of Census Facilities Reporting BSL-3 Capability (N= 245)

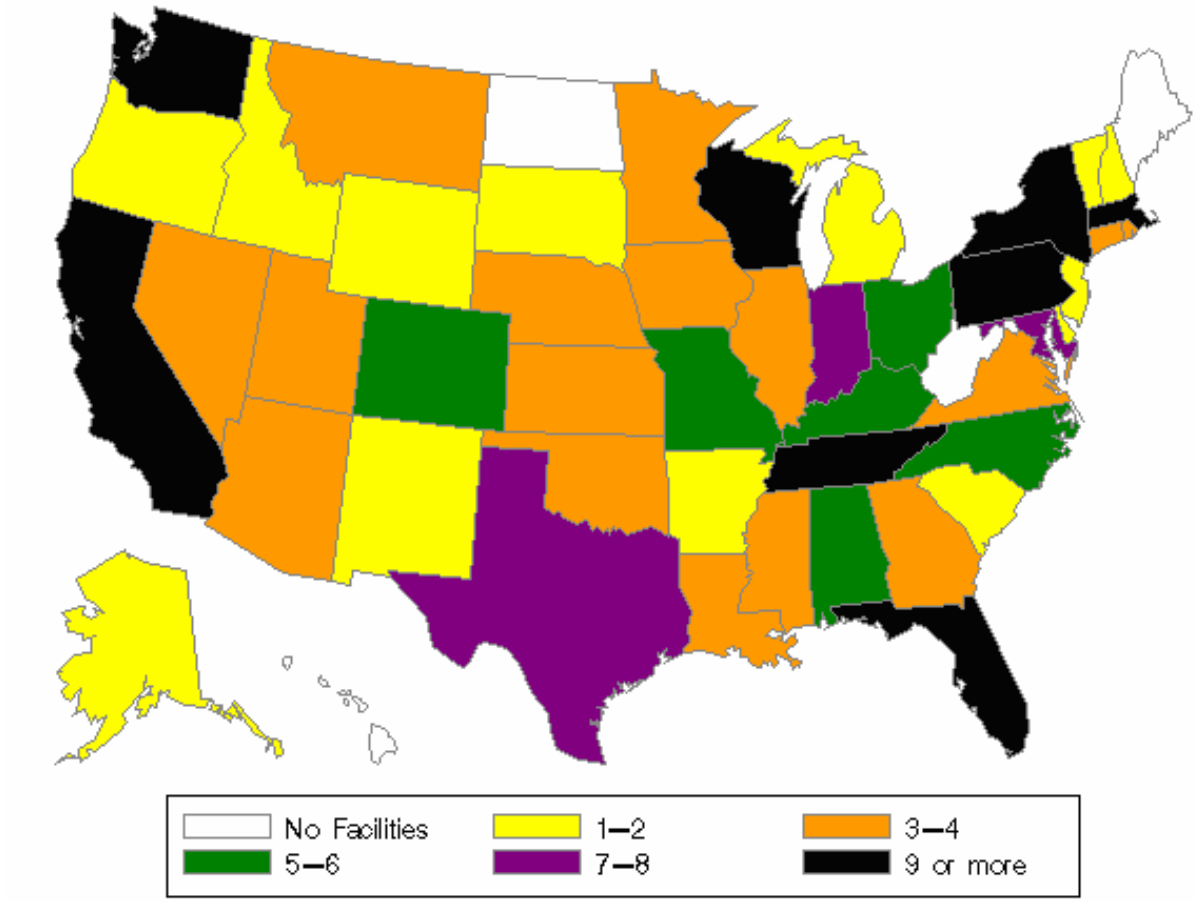
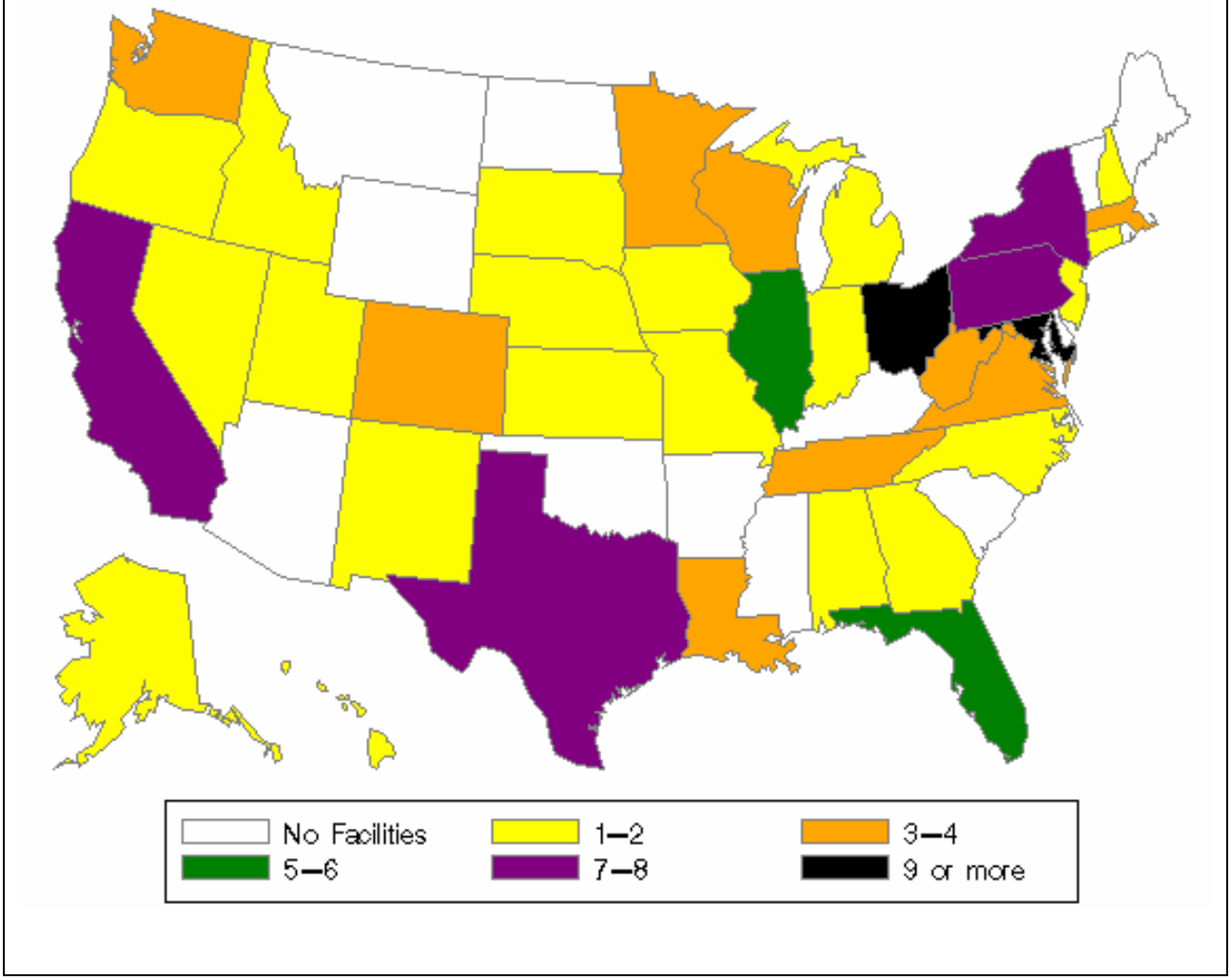


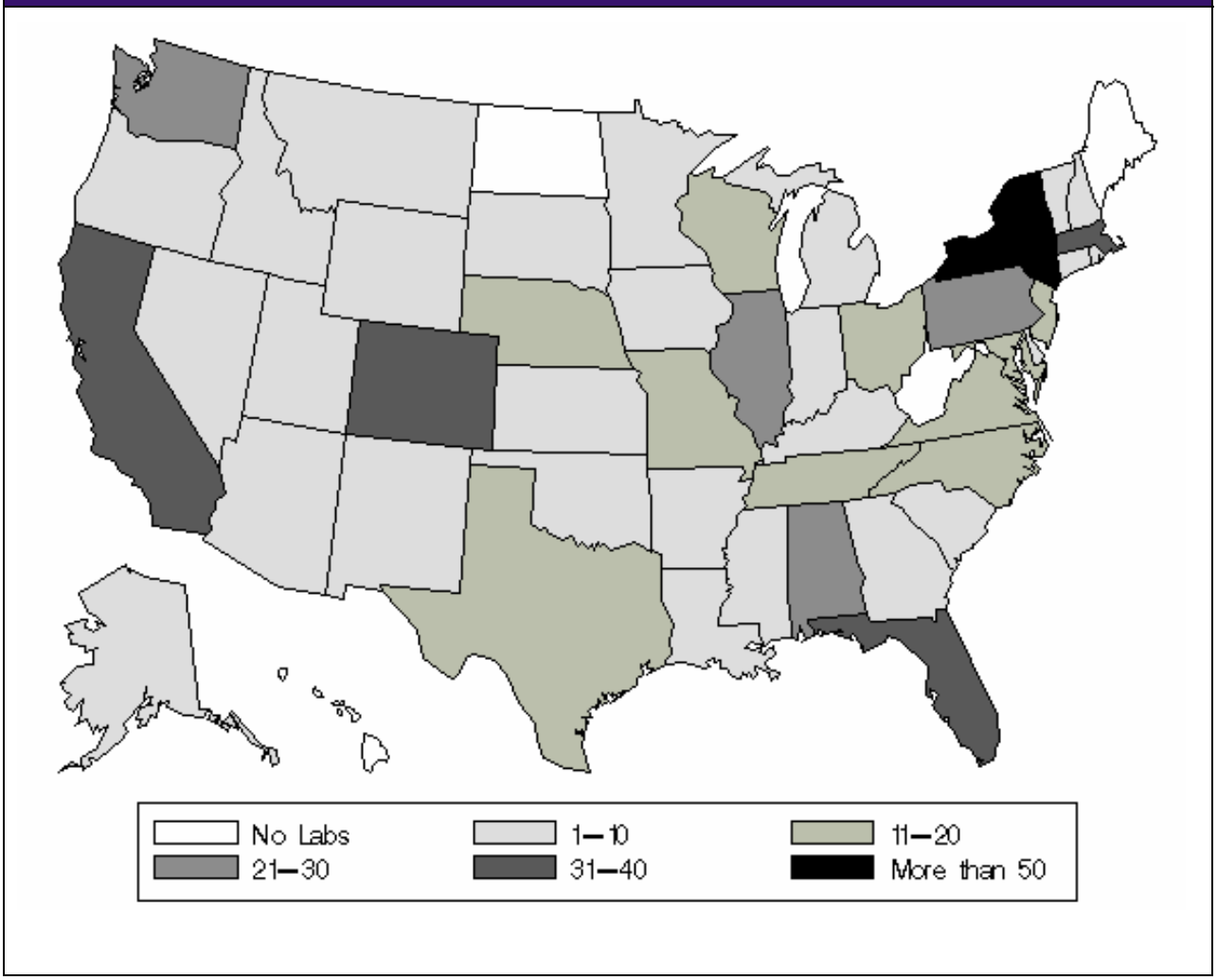
Exhibit 9 indicates the total number of BSL-3 capable facilities, per state, that were reported in responses to the Validation Study.

Exhibit 9: Geographic Distribution of Validation Survey Facilities Reporting BSL-3 Capability



In the Census Survey, each facility that reported BSL-3 capability was asked to indicate exactly how many separate laboratories existed within the facility. Exhibit 10 shows the total number of individual laboratories, per state, that were reported by facilities responding to the Census Survey.

Exhibit 10: Geographic Distribution of Laboratories with BSL-3 Capability Affiliated with the 245



4.2 RESPONSE TO QUESTIONS

In this section, aggregate responses to each of the five Census Survey questions are provided. Since only the Census Survey recipients answered these questions, the total number of valid online survey responses was 245 (145 Census plus 100 Overlap facilities).

Question 1. Please indicate the type of institution located on your organization's campus (check all that apply).

The first question of the Census Survey (after the qualifying question) asked the respondents to self-classify their institution. Because the respondents could check more than one response for

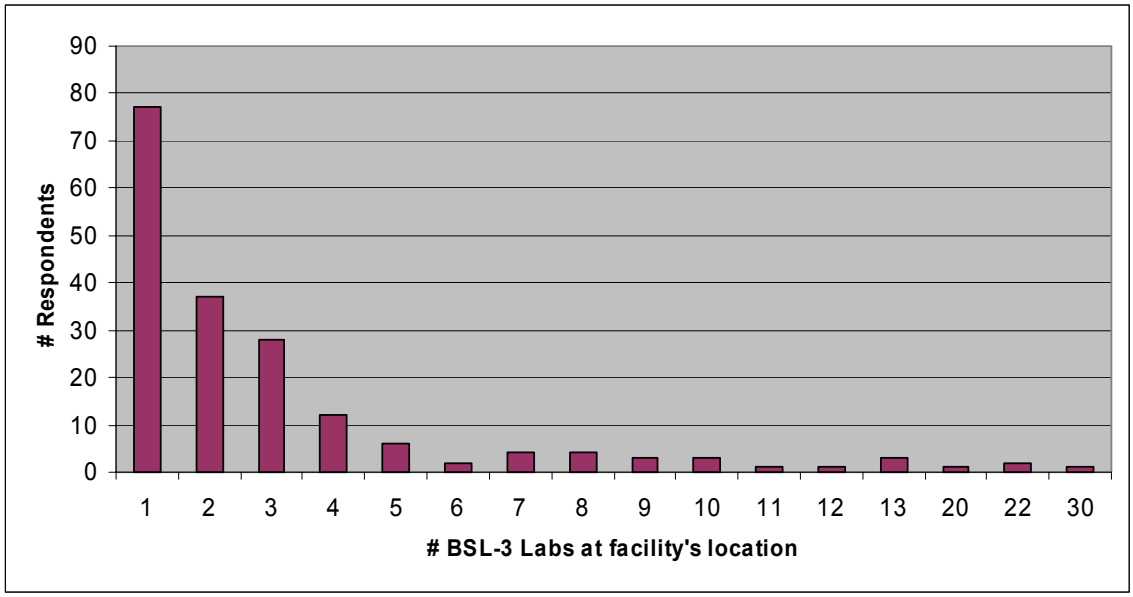
this question**,** the total number of responses (N=292) add up to a number greater than the total number of facilities reporting BSL-3 capable laboratories in the Census Survey (N=245).

Question 1 Responses: Types of Institutions Having BSL-3 Laboratories		
Response	N	% of BSL-3 Facilities
Academic	145	52.3%
Industrial/Commercial	19	6.9%
Clinical/Diagnostic	48	17.3%
Other	80	28.9%

Question 2. Please indicate how many BSL-3 laboratories are located on your organization's campus. Do not count a suite of laboratories as one laboratory. Count the number of distinct BSL-3 laboratories within each suite.

This question requested that facilities report the total number of distinct BSL-3 capable laboratories on the facility's campus. The total number of distinct BSL-3 capable laboratories associated with the 245 facilities responding to the Census Survey was 598. As shown in the graph below, most facilities indicated that they only had three or fewer BSL-3 laboratories on their campus. However, one facility indicated that they had up to 30 laboratories with BSL-3 capability.

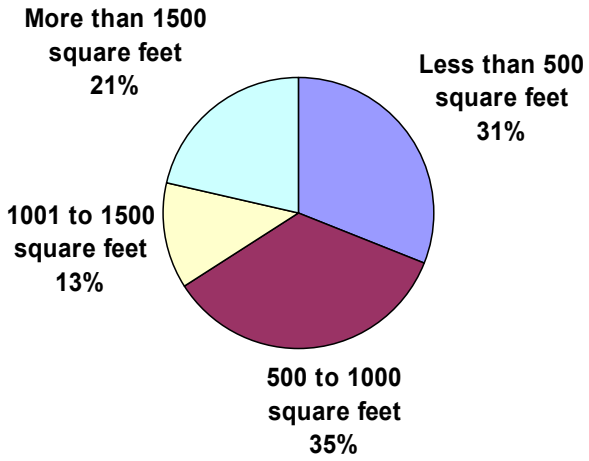
Question 2 Responses: Distribution of the Number of BSL 3 Laboratories per Responding Facility



Question 3. Please estimate the approximate square footage of qualified BSL-3 laboratory space on your organization's campus, assuming that a typical laboratory is approximately 250 square feet (please check only one.)

Question #3 asked the respondent to estimate the approximate combined square footage of all qualified BSL-3 laboratory space on their facility's campus by selecting one of the four 500 square foot intervals provided as shown in the following graph of results.

Question 3 Responses: Approximate Total Square Footage of BSL-3 Lab Space per Responding Facility



Question 4. Taking into account all of the BSL-3 laboratories on your organization's campus, please indicate the type(s) of work being conducted and complete the information in the following table. (Please check only one response per type(s) of work being conducted.)

Question #4 asked about the different types of work being performed in the BSL-3 capable laboratories reported by the facilities. According to the response, the majority of the BSL-3 capable laboratory space is currently being used for BSL-3 research. The second most common laboratory use is for clinical or diagnostic testing with BSL-3 agents. A small portion of the respondents indicated that their BSL-3 laboratories are used for production of products or other types of BSL-3 work (including work with non BSL-3 agents).

Question 4 Responses: Type of Work Being Performed in BSL-3 Labs at Responding Facilities

Work Performed	No Labs used for this purpose	Less than 1/3 is used for this purpose	Between 1/3 and 2/3 are used for this purpose	More than 2/3 is used for this purpose
BSL-3 research	69 (28.2%)	33 (13.4%)	32 (13.1%)	111 (45.3%)
Clinical or diagnostic testing with BSL-3 agents	135 (55.1%)	39 (15.9%)	33 (13.5%)	38 (15.5%)
Production of product	234 (95.5%)	4 (1.6%)	4 (1.6%)	3 (1.3%)
Other BSL-3 work	180 (73.5%)	19 (7.7%)	25 (10.2%)	21 (8.6%)

Question 5. Please indicate whether any of the BSL-3 laboratories on your organization's campus have the following capabilities. (Please check only one response for each item.)

In question #5, respondents were asked to indicate the different capabilities that their BSL-3 capable laboratories may have. The response in the following table shows both the number and percentage of responding facilities indicating that their facility had BSL-3 laboratories with the listed capabilities, as well as those laboratories having none of the listed capabilities at all. Conducting small animal studies and use of Good Laboratory Practices were the two most-often cited laboratory capabilities in the response to this question.

Question 5 Responses: BSL-3 Laboratory Capabilities		
Response	**N**	**% of BSL-3 Facilities**
Small animal studies	110	44.9%
FDA Good Laboratory Practices (GLP)	57	23.3%
Aerobiology studies	21	8.6%
Insect/arthropod studies	21	8.6%
None of the above	11	4.5%
FDA Good Manufacturing Practices (GMP)	10	4.1%
Large animal studies	8	3.3%
Current non-human primate studies	7	2.9%
Total	245	100.0%

5 DISCUSSION

In interpreting the results of this survey, several factors must be kept in mind. Because of the sensitive nature of the data being requested, respondents were promised that data would only be reported in aggregate and that all individual survey responses would be held confidential. All online survey respondents were required to acknowledge this stipulation by checking a Freedom of Information Act (FOIA) statement at the end of the survey. This statement acknowledged that "the response [shall be] exempt from disclosure under Exemption 4 of the Freedom of Information Act, as provided in the DHHS regulations implementing the FOIA."

In the solicitation materials, it was emphasized that this was a one-time data collection effort (i.e., "snapshot" in time) and that response data would not be maintained in any manner for future reference. To guard against unintended release of these survey results, the survey response database will be destroyed 120 days after delivery of this report (i.e., on or about September 1, 2005).

Another consideration is that survey recipients were under no obligation to respond to either the Census or Validation Survey. That an acceptable response rate was realized is, in large measure, a function of confidence in the leadership of NIAID and ASM and in the professional manner in which the survey was conducted by its administrators.

In addition to respondent concern over the release of what many perceive to be sensitive, proprietary, or classified information about the work being conducted in their facilities, there were also a number of other survey considerations that affected the outcome of the survey.

- ***Survey timing***: Although plans for conducting this survey began in the summer of 2005, OMB review and requests for survey modifications resulted in survey approval in October 2005.
- ***Narrow focus of mailing lists***: The Census Survey was limited by OMB to 1500 recipients. To more accurately identify a survey population that would likely have biocontainment facilities, a mailing list was derived from a compilation of the 1000 highest funded NIH grantees. Non-federal facilities were not included in the survey. In addition to the NIH listing, several focused memberships (PhRMA, BioIndustry, LRN Laboratories) were contacted to provide a more diverse population of facilities that would have biocontainment laboratories. After obtaining and compiling these lists, they were categorized subjectively according to facility type. It was determined from the onset of the survey to exclude facilities that were primarily conducting clinical and/or diagnostic work (e.g., hospitals and clinical reference laboratories).
- ***Short time frame for response***: There were only 150 days between OMB approval of the survey and the expiration date stipulated by OMB for the survey (February 28, 2005). Developing and producing the survey materials and survey Website occurred over the 60 days between OMB approval and the distribution date for the Census Survey of December 1, 2004. Census Survey respondents had 45 days to respond (including over the Christmas and New Year holidays). The Validation Survey respondents also had 45 days to respond between mid-January and the end of February 2005.

- ***Requesting sensitive data***: As indicated previously, it was recognized that some facilities would be reluctant to release information about sensitive, proprietary, or classified work being conducted in their facilities. This has especially been of concern because of recent adverse news stories about facilities conducting similar types of work and because of security provisions in the USA PATRIOT Act and 42 CFR73 *Possession, Use and Transfer of Select Agents and Toxins* which govern some laboratories conducting this type of work.
- ***No incentive to respond***: There were no real incentives for survey recipients either to respond or to complete the survey nor was there a government mandate to do so. Accordingly, the survey was made as simple as possible to reduce response burden. Virtually 100% of the facilities declaring BSL-3 capability were reported online, eliminating the need to complete and mail paper surveys.

There are several considerations regarding interpretation of the Validation Survey results. This survey, as opposed to the Census Survey, was not intended to collect data on the location, capacity, and status of BSL-3 laboratories in the US. It was requested by OMB as a means to validate whether the Census Survey had accurately captured a universe of facilities with BSL-3 capability. The fact that 100 facilities received both the Census and Validation Surveys as described in the overlap discussion in Section 4.1.1 suggests that the Census Survey population was an accurate reflection of the universe of facilities likely to have BSL-3 capabilities.

Finally, there also are several distinctions between the Validation and Census Surveys that should be considered. The Validation Survey sample consisted of individuals and not facilities. The survey was addressed to an individual ASM member who may or may not have had comprehensive and accurate information about the research facilities at their institution; the Census Survey was directed to the Environmental Health and Safety Officer at the facility. The only question a Validation Survey respondent needed to answer was with regard to whether their institution had laboratories that met the BSL-3 criteria. They were not asked any further questions as had been asked in the Census Survey (i.e., type of work, capacity, and size).

Further, the design of the Census Survey allowed for an escalation of follow-up to non-responding recipients; no follow-up was conducted with Validation Survey non-respondents.

In comparison to the Census Survey in which there 91 days were allowed for response, Validation Survey recipients had only 51 days in which to respond.

Despite these limitations, as demonstrated in Exhibit 5, the Census Survey achieved a nearly 50 percent response rate and the Validation Study a 38 percent response rate.

APPENDIX A

A1: Census Survey Cover Letter

A2: Census Survey Instruction Sheet

A3: Census Survey Response Card

A1: Census Survey Cover Letter

AMERICAN SOCIETY FOR MICROBIOLOGY

[DATE]

«DirTitle» «DirFstName» «DirMiName» «DirLstName»
«Organization_name»
«Address»
«City», «State» «Zip_code»

Dear Environmental Health and Safety Officer:

The American Society for Microbiology (ASM) is partnering with the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), to conduct a short survey of academic, biotechnology, and pharmaceutical facilities in the United States to collect information that will help better define the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment. BSL-3 containment is applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. The survey, developed by the NIAID with Office of Management and Budget approval, is being conducted with the assistance of Constella Health Sciences of Atlanta, Georgia.

In 2002, the NIAID convened a Blue Ribbon panel of experts to help define the Institute's research agenda for Category A agents. The Panel identified a "serious shortage of high containment laboratories in which to perform experiments using dangerous pathogens." NIAID's planned construction of containment facilities will expand national capacity to perform research on highly infectious agents. In Fiscal Year 2003, NIAID provided funding for two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). These new facilities will complement and support NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research and other NIAID research activities. The biocontainment laboratories will be available and prepared to assist national, state and local public health efforts in the event of a bioterrorism or infectious disease emergency.

The aggregated data collected in this important national survey will provide NIAID with needed information about current BSL-3 laboratory capacity in the US and will be used by the NIAID as an integral part of the planning process for construction of new facilities. Data provided by respondents is confidential; no site-specific information will be provided in the final report which will consist of aggregated data only.

The on-line survey questionnaire, which is posted on the ASM website at http://labsurvey.asm.org, consists of only 5 questions which can easily be completed in a few minutes by following the instructions on the enclosed page. If you are not the person who can answer the survey questions, please inform us by e-mailing labsurveyhelp@asmusa.org.

The NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases. The ASM is the largest single life science society composed of over 40,000 members involved in education, research, public health and clinical microbiology. We appreciate your willingness to participate in this important survey.

Sincerely,

James M. Tiedje, Ph.D.
President, ASM

1752 N Street, NW • Washington, DC • 20036-2804

A2: Census Survey Instruction Sheet

ASM/NIAID
BSL-3 Laboratory Survey

OMB No. 0925-0537
Expiration Date: 02/28/2005

INSTRUCTIONS TO RESPONDENTS

The purpose of this survey is to collect information that will better define the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment capabilities. We are soliciting responses from organizations that we believe have this capability in order to map the locations of BSL-3 laboratories by ZIP Code. To minimize burden we are only contacting one individual at each organization whom we believe can assist us with gathering this information.

A. The enclosed postcard lists the criteria that laboratories must posses to be considered a BSL-3 laboratory. Please take a moment to review these criteria. First, consider ***all*** of the laboratories affiliated with your organization and located on the campus within the ZIP Code printed below. If you can answer YES to *all* of the criteria listed on the postcard for ANY of the laboratories under consideration on the campus within this ZIP Code, you are eligible to complete the five questions on this survey.

Please log on to the Internet address given below to complete the questions about the BSL-3 laboratories in your facility by no later than January 14, 2005. Your Facility ID number, contact information and password are provided in the box below. If you do not have internet access or prefer to complete a paper survey, check the appropriate box on the postcard and return it to the pre-printed address on the card. *Please take time to do this today!* We will mail a survey to the pre-printed address within three days of receipt of the returned card. If you prefer that the survey be mailed to a different address, indicate the new address in the space provided on the postcard.

Survey Website address: http://labsurvey.asm.org

[Contact] **[Facility Name]** **[Address 1]** **[Address 2]** **[City], [St] [Zip+4]**	**Your Facility Identification Number is:** _____ **Your password is:** _____

If you ***cannot*** answer yes for all of the criteria listed on the survey for ANY of the laboratories under consideration within this ZIP Code, please take a few moments right now to logon onto the website above and provide this response.

B. Secondly, please let us know if there are laboratories meeting the BSL-3 criteria listed on the enclosed postcard, which are affiliated with your organization, but are located at addresses other than the one printed on this page. If so, please log on to the Internet address above and provide us with their address(es) and a contact person at the location that can provide information regarding the BSL-3 laboratories at their location or email us at labsurveyhelp@asmusa.org to provide this information.

Please take time to complete this survey today! In order to ensure that we have data that truly represents BSL-3 laboratory capability across the country, *it is critical that everyone who receives a survey provide either a positive or negative response.* If we do not hear from you within the next 30 days we will send you a postcard to remind you to complete and return this important survey.

If you have any questions regarding these instructions or the survey, please send an email to labsurveyhelp@asmusa.org

Thank you for your time and cooperation in completing this survey.

A3: Census Survey Response Card

Your Immediate Response is Requested!

AMERICAN SOCIETY FOR MICROBIOLOGY

OMB No. 0925-0537
Expiration Date: 02/28/2005

Biosafety Level 3 (BSL-3) containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Please review the BSL-3 criteria* listed below and consider all of the laboratories located on the campus at which you work to determine if any meet the following criteria:

1. Entry into the laboratory is by passage through a series of two self-closing doors (and the doors must be lockable).
2. The laboratory contains a Biological Safety Cabinet (see BMBL, Appendix A).
3. Air from the laboratory is ***not*** recirculated, but is exhausted outside or through HEPA filters.
4. Air pressure in the laboratory is less than (negative to) the air pressure in the surrounding workspace (e.g., other laboratories or office/administrative space).
5. All infectious waste generated in the laboratory is decontaminated before disposal off-site.

*See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

After considering the above criteria, please log on to the following internet site https://labsurvey.asm.org and enter the Facility ID and Password provided below to complete the two simple questions about the laboratories on the campus at which you work. Alternatively you can enter your responses below and return this postage-paid response card before February 14th, 2005.

1. **Please provide the nine digit Zip Code of the facility at which the laboratories under consideration are located:**

   _____ _____ _____ – _____ _____ _____ _____

   (Please use the following URL to determine the nine digit Zip Code of the facility at which the laboratories under consideration are located: http://zip4.usps.com/zip4/welcome.jsp.)

2. **Please review the statements below and check the appropriate box. (*Please check only one.*)**
   a) If you can answer YES to all of the criteria listed above for ANY of the laboratories under consideration, please check the box below.

   ☐ Yes, one or more laboratories at this facility meet(s) Biosafety Level 3 criteria.

   b) If you ***cannot*** answer YES to all of the criteria listed above for ANY of the laboratories under consideration, please check the box below.

   ☐ No laboratories at this facility meet Biosafety Level 3 criteria.

[Mailing List Contact]
[Mailing List Facility Name]
[Mailing List Address 1]
[Mailing List Address 2]
[Mailing List City, State Zip]

Facility ID: XXXXXX
Password: XXXXXX

BARCODE

ASM/NIAID BSL-3 Laboratory Survey
PO Box 95743
Atlanta, GA 30347-0743

No Postage Necessary if mailed in the United States

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO 365, ATLANTA, GA

POSTAGE WILL BE PAID BY ADDRESSEE

ASM/NIAID BSL-3 Survey Response
PO Box 95743
Atlanta, GA 30347-0743

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PA Number (0925-0537). Do not return the completed form to this address.

APPENDIX B

B1: Validation Survey Cover Letter

B2: Validation Survey Instruction Sheet

B3: Validation Survey Response Card

B1: Validation Survey Cover Letter

AMERICAN SOCIETY FOR MICROBIOLOGY

[DATE]

«DirTitle» «DirFstName» «DirMiName» «DirLstName»
«Organization_name»
«Address»
«City», «State» «Zip_code»

Dear Environmental Health and Safety Officer:

The American Society for Microbiology (ASM), in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), conducted a survey of US academic, biotechnology, and pharmaceutical facilities in December 2004, to help determine the location, capacity and status of laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment. ASM and NIAID are conducting a follow-up validation survey intended to evaluate the comprehensiveness of the population of institutions identified for the December census survey. Although the census survey is expected to include nearly all BSL-3 capable laboratories, there may be BSL-3 laboratories that were not included in the surveyed populations. We, therefore, are soliciting responses from a random sample of ASM members who were not part of the census survey but who work at institutions that may have BSL-3 capable laboratories.

BSL-3 containment is applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agenst that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. The census survey, developed by the NIAID with Office of Management and Budget (OMB) approval and this validation survey are being conducted with the assistance of Constella Health Sciences of Atlanta, Georgia.

In 2002, the NIAID convened a Blue Ribbon panel of experts to help define the Institute's research agenda for Category A agents. The Panel identified a "serious shortage of high containment laboratories in which to perform experiments using dangerous pathogens." NIAID's planned construction of containment facilities will expand national capacity to perform research on highly infectious agents. In Fiscal Year 2003, NIAID provided funding for two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). These new facilities will complement and support NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research and other NIAID research activities. The biocontainment laboratories will be available and prepared to assist national, state and local public health efforts in the event of a bioterrorism or infectious disease emergency.

The aggregated data collected in the census survey of BSL-3 capable laboratories will provide NIAID with needed information aobut current BSL-3 laboratory capacity in the US and will be used by NIAID as an integral part of the planning process for construction of new facilities and renovation of existing laboratories. The data collected in this validation survey will enable NIAID to assess the comprehensiveness and effectiveness of the census survey. Data provided by respondents is confidential; only aggregated data and no site specific information will be provided in the final report.

The secure on-line survey questionnaire, which is posted on the ASM website at http://labsurvey.asm.org, consists of only two questions which can easily be completed in a few minutes by following the instructions on the enclosed page. If you are not the person who can answer the survey questions, please inform us by e-mailing labsurveyhelp@asmusa.org.

The NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases. The ASM is the largest single life science society composed of over 40,000 members involved in education, research, public health and clinical microbiology. We appreciate your willingness to participate in this important survey.

Sincerely,

James M. Tiedje, Ph.D.
President, ASM

1752 N Street, NW • Washington, DC • 20036-2804

B2: Validation Survey Instruction Sheet

ASM/NIAID
BSL-3 Laboratory Survey

OMB No. 0925-0537
Expiration Date: 02/28/2005

INSTRUCTIONS TO RESPONDENTS

The purpose of this survey is to evaluate the accuracy of a recently administered study which aimed to collect information that would better define the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment capabilities. We are soliciting responses from individuals who were not part of the original study and who work at an organization that may have BSL-3 capable laboratories in order to evaluate the comprehensiveness of the population identified for the census survey.

The enclosed postcard lists the criteria that laboratories must posses to be considered a BSL-3 laboratory. Please take a moment to review these criteria. Please consider ***all*** of the laboratories affiliated with your organization and located on the campus at which you work.

Next, log on to the Internet address given below to complete the two simple questions about the laboratories at your facility by no later than February 14th, 2005. Your Facility ID number, contact information and password are provided in the box below. If you do not have internet access or do not wish to complete the survey online, then you may complete the enclosed postage-paid response card and return it to the pre-printed address on the card before February 14th, 2005.

Survey Website address: https://labsurvey.asm.org

[Contact] **[Facility Name]** **[Address 1]** **[Address 2]** **[City], [St] [Zip+4]**	**Your Facility Identification Number is:** __ __ __ __ __ __ **Your password is:** __ __ __ __ __ __

Please take time to complete this important survey today! In order to ensure that we have data that truly represents BSL-3 laboratory capability across the country, *it is critical that everyone who receives a survey provide a response*, whether your organization has BSL-3 capable facilities or not.

If you have any questions regarding these instructions or the survey, please send an email to labsurveyhelp@asmusa.org

Thank you for your time and cooperation in completing this survey.

B3: Validation Survey Response Card

OMB No. 0925-0537
Expiration Date: 02/28/2005

Biosafety Level 3 (BSL-3) containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Please review the BSL-3 criteria* listed below and consider all of the laboratories located on the campus at the address printed below to determine if any meet the following criteria:

1. Entry into the laboratory is by passage through a series of two self-closing doors (and the doors must be lockable).
2. The laboratory contains a Biological Safety Cabinet (see BMBL, Appendix A).
3. Air from the laboratory is ***not*** recirculated, but is exhausted outside through HEPA filters.
4. Air pressure in the laboratory is less than (negative to) the air pressure in the surrounding workspace (e.g., other laboratories or office/administrative space).
5. All infectious waste generated in the laboratory is decontaminated before disposal off-site.

*See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

If you can answer YES to all of the criteria listed above for ANY of the laboratories under consideration, you are eligible to complete this survey. Please log on to the Survey Website (http://labsurvey.asm.org) and enter the Facility ID and password provided below to complete the five simple questions about the BSL-3 laboratories in your facility.

If your organization has ***additional*** laboratories meeting BSL-3 criteria but they are not located within the Zip Code printed below, please log on to the Website listed above and provide us with their address(es) or email us at labsurveyhelp@asmusa.org to provide this information. If you ***cannot*** answer yes for all of the criteria in the list above for ANY of the laboratories located within the Zip Code printed below or at locations other than the Zip Code printed below, we would still like to receive a response from you. You may either log on to the Website listed above and provide your response, or you can check the box below and return this postage-paid response card as soon as possible.

☐ **No laboratories under consideration on the campus within the ZIP Code printed below or at other locations meet Biosafety Level 3 criteria.**

Facility ID: XXXXX [BARCODE]
Password: XXXXX
[Mailing List Contact]
[Mailing List Facility Name]
[Mailing List Address 1]
[Mailing List Address 2]
[Mailing List City, State Zip]

Corrected Address:

If you do not have internet access or prefer to complete a paper survey check the box below and fold and return this postage-paid card to the pre-printed address on the card. We will mail you a survey to the address above. If you prefer that it be mailed to a different address, please indicate the new address in the space provided.

☐ **Please mail a survey to the address above.**

Your Immediate Response is Requested!

AMERICAN SOCIETY FOR MICROBIOLOGY

ASM/NIAID BSL-3 Laboratory Survey
PO Box 95743
Atlanta, GA 30347-0743

No Postage Necessary if mailed in the United States

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO 365, ATLANTA, GA
POSTAGE WILL BE PAID BY ADDRESSEE

ASM/NIAID BSL-3 Laboratory Survey Response
PO Box 95743
Atlanta, GA 30347-0743

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0537). DO NOT return the completed form to this address.

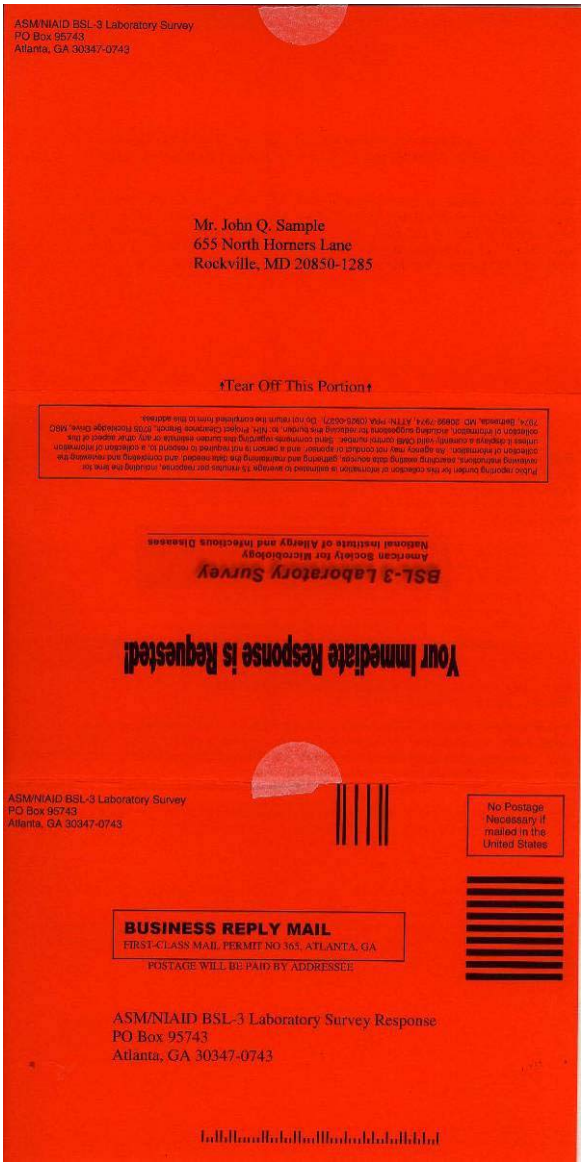
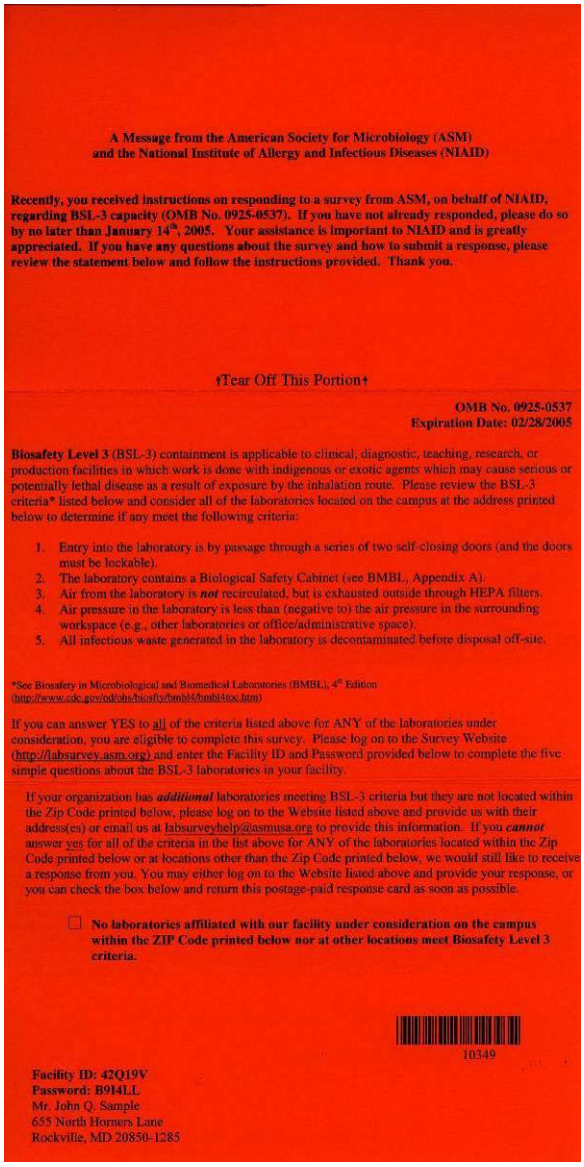
APPENDIX C

C1: First Reminder Postcard

C2: Second Reminder Postcard

C3: Final Plea Letter

C1: First Reminder Postcard

Front	Back
	

**A Message from the American Society for Microbiology (ASM)
and the National Institute of Allergy and Infectious Diseases (NIAID)**

Recently, you received instructions on responding to a survey from ASM, on behalf of NIAID, regarding BSL-3 capacity (OMB No. 0925-0537). If you have not already responded, please do so by no later than January 14th, 2005. Your assistance is important to NIAID and is greatly appreciated. If you have any questions about the survey and how to submit a response, please review the statement below and follow the instructions provided. Thank you.

†Tear Off This Portion†

**OMB No. 0925-0537
Expiration Date: 02/28/2005**

Biosafety Level 3 (BSL-3) containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Please review the BSL-3 criteria* listed below and consider all of the laboratories located on the campus at the address printed below to determine if any meet the following criteria:

1. Entry into the laboratory is by passage through a series of two self-closing doors (and the doors must be lockable).
2. The laboratory contains a Biological Safety Cabinet (see BMBL, Appendix A).
3. Air from the laboratory is ***not*** recirculated, but is exhausted outside through HEPA filters.
4. Air pressure in the laboratory is less than (negative to) the air pressure in the surrounding workspace (e.g., other laboratories or office/administrative space).
5. All infectious waste generated in the laboratory is decontaminated before disposal off-site.

*See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

If you can answer YES to all of the criteria listed above for ANY of the laboratories under consideration, you are eligible to complete this survey. Please log on to the Survey Website (http://labsurvey.asm.org) and enter the Facility ID and Password provided below to complete the five simple questions about the BSL-3 laboratories in your facility.

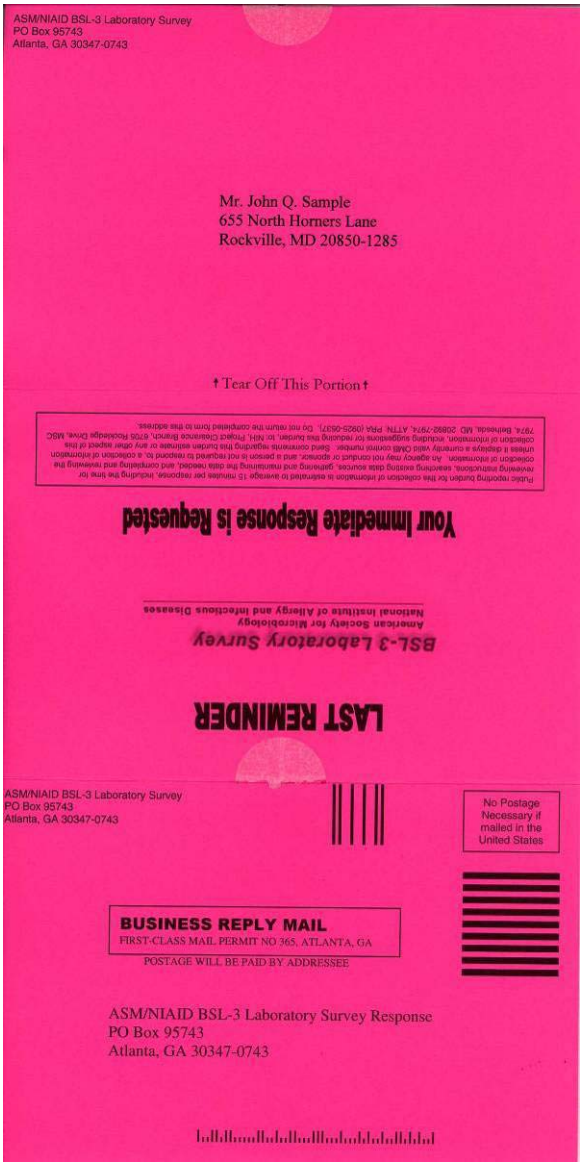
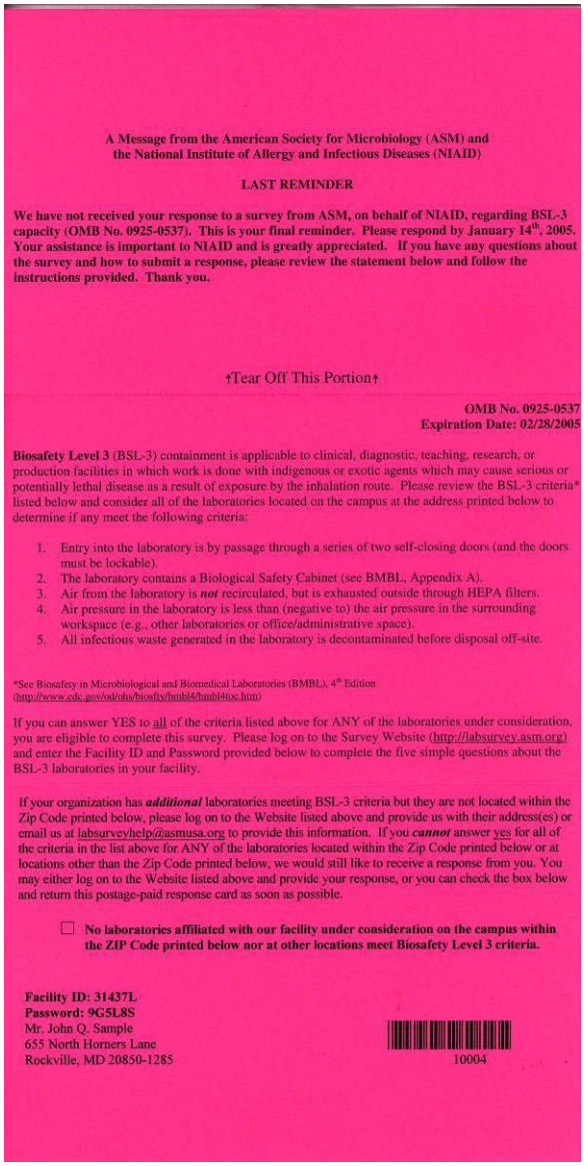
If your organization has ***additional*** laboratories meeting BSL-3 criteria but they are not located within the Zip Code printed below, please log on to the Website listed above and provide us with their address(es) or email us at labsurveyhelp@asmusa.org to provide this information. If you ***cannot*** answer yes for all of the criteria in the list above for ANY of the laboratories located within the Zip Code printed below or at locations other than the Zip Code printed below, we would still like to receive a response from you. You may either log on to the Website listed above and provide your response, or you can check the box below and return this postage-paid response card as soon as possible.

☐ **No laboratories affiliated with our facility under consideration on the campus within the ZIP Code printed below nor at other locations meet Biosafety Level 3 criteria.**

10349

**Facility ID: 42Q19V
Password: B9I4LL**
Mr. John Q. Sample
655 North Horners Lane
Rockville, MD 20850-1285

C2: Second Reminder Postcard

Front	Back
	

A Message from the American Society for Microbiology (ASM) and the National Institute of Allergy and Infectious Diseases (NIAID)

LAST REMINDER

We have not received your response to a survey from ASM, on behalf of NIAID, regarding BSL-3 capacity (OMB No. 0925-0537). This is your final reminder. Please respond by January 14th, 2005. Your assistance is important to NIAID and is greatly appreciated. If you have any questions about the survey and how to submit a response, please review the statement below and follow the instructions provided. Thank you.

†Tear Off This Portion†

OMB No. 0925-0537
Expiration Date: 02/28/2005

Biosafety Level 3 (BSL-3) containment is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Please review the BSL-3 criteria* listed below and consider all of the laboratories located on the campus at the address printed below to determine if any meet the following criteria:

1. Entry into the laboratory is by passage through a series of two self-closing doors (and the doors must be lockable).
2. The laboratory contains a Biological Safety Cabinet (see BMBL, Appendix A).
3. Air from the laboratory is ***not*** recirculated, but is exhausted outside through HEPA filters.
4. Air pressure in the laboratory is less than (negative to) the air pressure in the surrounding workspace (e.g., other laboratories or office/administrative space).
5. All infectious waste generated in the laboratory is decontaminated before disposal off-site.

*See Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

If you can answer YES to all of the criteria listed above for ANY of the laboratories under consideration, you are eligible to complete this survey. Please log on to the Survey Website (http://labsurvey.asm.org) and enter the Facility ID and Password provided below to complete the five simple questions about the BSL-3 laboratories in your facility.

If your organization has ***additional*** laboratories meeting BSL-3 criteria but they are not located within the Zip Code printed below, please log on to the Website listed above and provide us with their address(es) or email us at labsurveyhelp@asmusa.org to provide this information. If you ***cannot*** answer yes for all of the criteria in the list above for ANY of the laboratories located within the Zip Code printed below or at locations other than the Zip Code printed below, we would still like to receive a response from you. You may either log on to the Website listed above and provide your response, or you can check the box below and return this postage-paid response card as soon as possible.

☐ **No laboratories affiliated with our facility under consideration on the campus within the ZIP Code printed below nor at other locations meet Biosafety Level 3 criteria.**

Facility ID: 31437L
Password: 9G5L8S
Mr. John Q. Sample
655 North Horners Lane
Rockville, MD 20850-1285

10004

C3: Final Plea Letter

AMERICAN SOCIETY FOR MICROBIOLOGY

January 11, 2005

Environmental Health and Safety Officer
«Organization_name»
«Address»
«City», «State» «Zip_code»

Facility ID: XXXXXX
Password: XXXXXX

Dear Environmental Health and Safety Officer:

On December 1st, 2004 the American Society for Microbiology (ASM), on behalf of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), mailed a survey solicitation to your organization regarding Biosafety Level 3 (BSL-3) capacity. This is a very important survey and as of January 11, 2005,a response has not been received from your organization. It is extremely important that someone from your facility respond to this survey, whether your organization has BSL-3 capable facilities or not. In order to ensure that we have data that truly represents BSL-3 laboratory containment capability across the country, it is critical that every laboratory who receives a survey provide a prompt response by no later than February 4, 2005. If you are not the person who can answer the survey or if you have any questions, please contact us by e-mailing labsurveyhelp@asmusa.org.

The purpose of this short survey is to collect information that will help better define the location, capacity and status of existing and operating US laboratory facilities that incorporate Biosafety Level 3 (BSL-3) containment. BSL-3 containment is applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. The aggregated data collected in this important national survey will provide NIAID with needed information about current BSL-3 laboratory capacity in the US and will be used by the NIAID as an integral part of the planning process for construction of new facilities.

In 2002, the NIAID convened a Blue Ribbon panel of experts to help define the Institute's research agenda for Category A agents. The Panel identified a "serious shortage of high containment laboratories in which to perform experiments using dangerous pathogens." NIAID's planned construction of containment facilities will expand national capacity to perform research on highly infectious agents. In Fiscal Year 2003, NIAID provided funding for two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). These new facilities will complement and support NIAID's Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research and other NIAID research activities. The biocontainment laboratories will be available and prepared to assist national, state and local public health efforts in the event of a bioterrorism or infectious disease emergency.

The survey was developed by NIAID with Office of Management and Budget (OMB) approval and all of the site-specific information submitted in response will be exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), as provided in the DHHS regulations implementing the FOIA. Results will not be used to generate public quantitative claims but will be restricted to internal planning operations. Neither the NIAID nor the American Society of Microbiology will establish or maintain a database of BSL-3 facilities based upon the results of this survey.

The on-line survey questionnaire, which is posted on the ASM website at https://labsurvey.asm.org, consists of only five questions which can easily be completed in a few minutes by logging onto the website using the Facility ID and Password provided above. Due to the sensitive nature of the questionnaire, a secure form has been developed to protect the integrity of the responses and respondents. The data will be transmitted over a secure server, secured by firewalls, and protected by a Secure Sockets Layer (SSL) or "https" protocol, which will encrypt the information being submitted.

We appreciate your prompt response and willingness to reply to this important survey.

Sincerely,

James M. Tiedje, Ph.D.
President, ASM

1752 N Street, NW • Washington, DC • 20036-2804