# New York State Department of Health

# Chemical/Biological/Radiological/ Nuclear Autonomous Detection System Laboratory Response Plan

# Template

***Version date: 8/26/2010***

***"The information contained in this document is CONFIDENTIAL. No information from this document shall be released when such release would jeopardize efforts to prepare for a public health emergency, and thereby endanger the life or safety of the people of the state or locality".***

## Foreword: Background and Authority

New York State (NYS) Public Health Law Section 502 authorizes the Commissioner of Health to issue certificates of approval to environmental laboratories, and empowers the Commissioner to adopt and amend regulations for implementing the provisions and intent of Section 502. Section 502 requires all laboratories performing environmental analysis on samples collected in NYS to hold certificates of approval and authorizes the Commissioner to establish standards, and technical and educational qualifications for staff, to ensure that tests are performed in an accurate and reliable manner.

Accurate and reliable identification of critical agents in environmental samples is crucial to appropriate and timely public health response to potential biological or chemical terrorism events, and/or other such incidents posing a significant public health threat. Department Regulations, 10 New York Codes Rules and Regulations (NYCRR) Subpart 55-2.14, sets forth standards for certification of environmental laboratories that examine samples for critical agents using an Autonomous Detection System (ADS), an automated, real-time, self-contained sampling and analytical system for detection of critical agents, with the capability of issuing real-time alerts. To address the issues raised by real-time analysis and alerting, this regulation requires the following:

1) oversight by highly qualified personnel experienced in the technology;
2) procedures for ongoing ADS monitoring, security and emergency shutdown;
3) model-specific training of ADS operators;
4) adequate protocols for director-level oversight of multiple and/or remote ADS stations, and;
5) Department approval of a response plan to be implemented by the laboratory whenever an ADS signal is triggered;
6) ***documented collaboration among laboratories and all identified public health, law enforcement and public safety authorities through the development of a mutually agreed-upon Response Plan***

As a fundamental component of the Laboratory Response Plan, the regulation requires laboratories to notify the New York State Department of Health (NYSDOH) of any analytical finding indicating the presence of a critical agent and to utilize confirmatory testing as an indicator of a system's functioning and validity. As such, it is crucial that each facility develop and implement Response Plans to a positive ADS signal, and to notify all appropriate public health, law enforcement and public safety parties within specified timeframes. 10 NYCRR Subpart 55-2.14 requirements promote clear communication of test results for various agents, and permits NYSDOH to determine the need for confirmatory testing. As a result, this regulation requires that the Response Plan is developed and agreed upon in collaboration with state public health and public safety authorities, and comparable local authorities whenever applicable, that are responsible for confirming, responding to, or remediation and incident involving critical agents. This Response Plan must also be accompanied with documentation of approval by all state and /or local public health, law enforcement and public safety authorities identified within the plan; and a signed attestation of agreement between the certified laboratory and the client(s) on whose property an ADS is situated that the response plan will be followed.

## *Disclaimer*

This template was developed to provide general guidance as to the key components required in the ADS Response Plan, a requirement for the application. This sample plan is a guide for determining subjects, partnerships, capacities and issues appropriate for the community in which the ADS resides. It is not intended to be a "boiler-plate," each community may have different partners and entities that will be included in the response operations.

This template contains **sample** language and guidance for use by the applicants and their emergency planning partners, applicants should contact local emergency response partners to ascertain additional local guidance.

Items that may pre-exist in Annexes, Appendices, or Attachments to current plans or other agency plans need to be properly cross referenced with plan title, section or page as applicable to the planning component. It is not expected that these plans external to the applicant, be submitted with the application.

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## Section I: Plan Administration *(Signature Page)*

### A. Acknowledgements[2]

1. ADS Representatives

*<Insert ADS Owner>*

Name:
Title:
Agency:
Date:

*<Insert ADS Lab Director>*

Name:
Title:
Agency:
Date:

*<Insert ADS Operator>*

Name:
Title:
Agency:
Date:

*<Insert Other as applicable>*

Name:
Title:
Agency:
Date:

2. Emergency Management/Public Health and Public Safety Response Partnerships

*<Insert Law Enforcement Agency>*

Name:
Title:
Agency:
Date:

*< Insert Emergency Management>*

Name:
Title:
Agency:
Date:

*< Insert Fire>*

Name:
Title:
Agency:
Date:

*< Insert Hazardous Material Response>*

Name:
Title:
Agency:
Date:

[2] *This page will require the Titles and signatures of those agencies required to contribute this plan, include additional agencies as needed.*

*< Insert Emergency Medical Services>*

Name:
Title:
Agency:
Date:

*< Insert Hospital(s)>*

Name:
Title:
Agency:
Date:

*< Insert Public Health>*

Name:
Title:
Agency:
Date:

*< Insert Other as applicable>*

Name:
Title:
Agency:
Date:

*< Insert Other as applicable >*

Name:
Title:
Agency:
Date:

*< Insert Other as applicable>*

Name:
Title:
Agency:
Date:

## B. Plan Distribution & Update Cycle

1. Distribution Plan
2. Revision Cycle
3. Revision Record

| Revision No. | Date | Responsable Person | Description of Change |
|---|---|---|---|
| 0 | 04/12/10 | QA Officer | (*example)* Initial Release |
| 1 | 06/09/10 | QA Officer | *(example )*Inserted Appendix A (SOPs), additional references |
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## C. Annual Review

If the Response Plan has not been revised in the past 12 months of the date listed in the Revision Record, the review of the Response Plan is to be documented **annually**. The documentation of this review is noted below.

**Record of Review**

| Signature | Title | Date |
|---|---|---|
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |
| Signature | Title | Date |

## D. Training Record and Signature Log

The following laboratory staff have read and agree to follow this Response Plan on an **annual** basis. In addition, the staff listed below have received annual training, have read the contents of the Response Plan, have exercised their responsible roles annually, and recognize that they are responsible for signing and/or initialing laboratory records.

| Signature | Name | Initials | Date |
|---|---|---|---|
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## E. Introduction & Guidelines

### 1. General Considerations

This Response Plan template may be used as a guide for identifying components of a comprehensive response to a public health / public safety threat; specifically following a signal from an ADS. The content of this draft was created following a comprehensive review of both federal and NYS emergency operations and continuity of operations plans, and is intended to assist in the identification of all required content areas for an effective response. However, this template is not intended to be a 'one-size-fits-all' approach, and every certified laboratory must develop a plan that is appropriate for response to their specific ADS and the agencies identified to respond.

While this template is consistent with federal and state expectations of such responses, the NYSDOH Environmental Laboratory Approval Program (ELAP) recognizes that depending upon the business model or corporate organization of the certified laboratory related to the building owners and/or other occupants, all aspects of this plan may not be within the direct authority of the certified laboratory. ELAP has outlined two possible relationships between the laboratory and the building owners and/or other occupants, which may alter the scope of this Response Plan (*Figure 1*).

### 2. Scenario #1

In **Scenario #1,** the laboratory occupies a physical location in which the Technical Director oversees all aspects of the ADS operation, quality assurance, and regulatory compliance remotely. In this model, one laboratory may oversee the monitoring of several ADSs if the technology of the network allows such real-time monitoring and signaling to a remote location. Since, the ADS may be operated on behalf of a client/building occupant that may not own the building itself the laboratory's role in the response efforts to a signal may be more limited. Response roles to an ADS signal in this scenario would include (but not be limited to):

a) Technical oversight, quality control, and maintenance of the ADS;
b) Training and competency of ADS Operators;
c) Verification of signal;
d) Notification of presumptive positive to client;
e) Coordination of sample collection and verification by a confirmatory laboratory;
f) Procedures to render ADS inoperative if signal is found to be false or unit is malfunctioning;
g) chain of custody procedures;
h) and records retention.

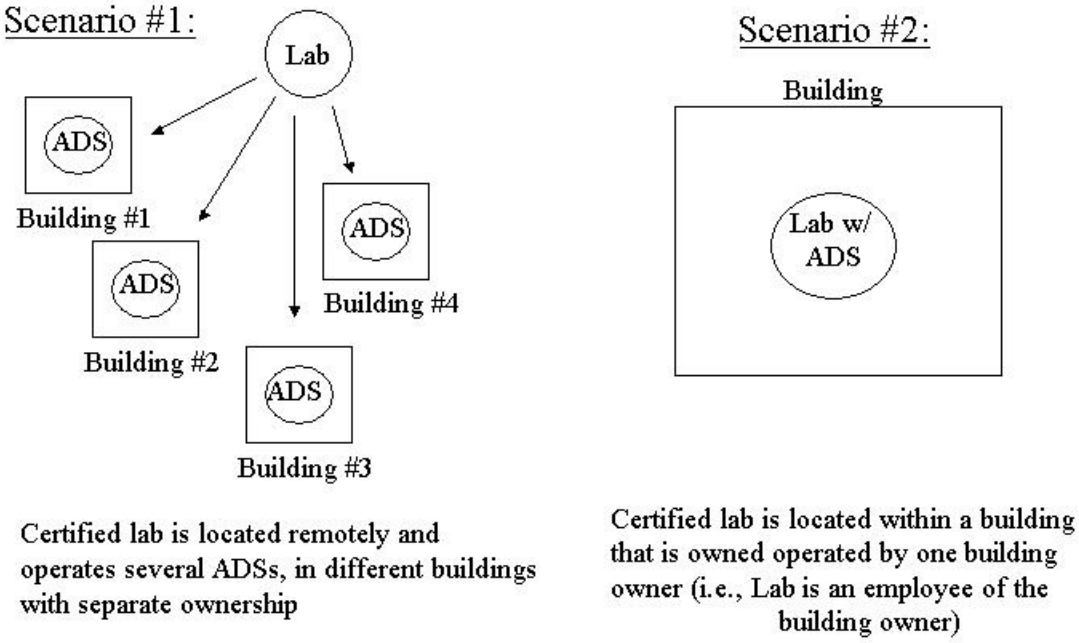
In this scenario, the client and/or building owner would be responsible for other aspects of response to an ADS signal including (but not limited to): medical evaluation of all building occupants, potential decontamination and/or medical treatment in collaboration with local health and safety partners, risk communication, and reoccupation.

3. Scenario #2

In **Scenario #2,** the laboratory is both physically located and owned by a single building owner. In this scenario, the building owner is legally responsible for the activities of the laboratory and may chose to coordinate the response to an ADS signal in a unified manner that is consistent with their building operations.

In either case, the certified laboratory and/or building owners need to consider their roles and responsibilities in the deployment and response to an ADS signal, in addition to their ability to support a state response to an emergency. These entities must work to collaboratively develop pre-event planning along side responding public health, law enforcement and public safety partners, to ensure an effective response. Participation in local drills and/or exercises will also assist in ensuring that all parties clearly understand their own roles, as well as the expectations of others.

Figure 1. Potential Certified Lab and Building Owner Relationships



## Section II: Scope

In this section of the Response Plan, the applicant to describe the intent /purpose for deploying an ADS. This section should include details regarding which critical agents that are being monitored by the ADS (i.e., biological, chemical, and/or radiochemical agents, etc.), identify which technology/technologies are being utilized, and outline the limits of detection (LOD) of the ADS unit. This section should also outline why monitoring is critical to the public health and safety of this facility.

## Section III: Planning Assumptions

### A. Assumptions

10 NYCRR Subpart 55-2.14 requires regulatory oversight of laboratories that detect critical agents via incidental (i.e., intentional) release or exposure. However, the threat may originate either inside or outside the laboratory and/or building. This section of the Response Plan prompts the applicant to outline its Planning Assumptions for ADS operation and response to an ADS signal. For example, following a site specific risk assessment (including airflow modeling), if the Planning Assumption of this laboratory identifies that the most likely route of exposure to be the intentional release of a critical agent through the building's HVAC system, then that would clarify the logic for placing the ADS in/nearby the HVAC unit.

All Laboratory Response Plans should have at a minimum the following Planning Assumptions:

1. Emergencies or disasters with public health implications may occur with little or no warning and may be overwhelming for local, regional, and state public health agencies.
2. The extent of the response will be guided by the number of individuals affected and the nature of the agent.
3. An ADS signal must be interpreted as the positive identification of a chemical, biological, radiological or nuclear critical agent, and must be immediately acted upon according to the Response Plan
4. A public health emergency, natural disaster or terrorist attack will require an immediate and sustained public health response.
5. Planning partners included in this Response Plan will not relinquish statutory obligations and responsibilities while involved in a response to incidents covered by this plan.
6. Planning partners will maintain internal standard operating procedures and/or agency/institution specific response plans to be used as the basis of their own response. These plans will be reviewed and updated routinely.
7. All ADS signals to the presence of a critical agent will be interpreted as a deliberate attack and must be reported to law enforcement officials for the forensic examination and the identification of criminal evidence.

### B. Responsible Parties

This section on Planning Assumptions must also outline the key public health, law enforcement and public safety partners on whose authority or guidance the laboratory will initiate the response to an ADS signal. For example, the immediate response to a signal may call for (but not limited to) the disabling of an HVAC unit (to stop airflow circulation), evacuation of staff, and notification of local law enforcement and public health officials. During the pre-event planning and development of this Response Plan, the applicant must outline the responsible parties that will either assist or provide formal guidance to the laboratory regarding these actions. The partnering agencies should include at a minimum, Law Enforcement, Emergency Management, Fire, Hazardous Material Response, Emergency Medical Services, and Public Health.

## Section IV: Concept of Operations (ConOps)

The purpose of this section is to identify, to the extent practical, the anticipated chain of events that will occur during a response to an ADS signal. Since each situation will likely present unique concerns, it may be difficult to know in advance all aspects of a response. However, this section of the plan allows the applicant to identify the key steps and thought processes surrounding the initial recognition / verification of a signal, notification of a predetermined list of public health, law enforcement and safety agencies, an outline of critical response decisions, and activation of the response plan. This section of the plan outlines the laboratory's mechanism to address the following areas of initial response.

### A. Triggered Signal

1. Notification Procedures:

The laboratory must identify a pre-determined list of public health, law enforcement and safety agencies that will be notified, along with the pre-scripted message that will be conveyed. This pre-scripted message must be relayed immediately following an ADS signal, and must include (at a minimum) identification of the ADS location, that the signal indicates the "presumptive" or "preliminary" detection of a critical agent, and the identity of the presumptive agent (i.e., biological, chemical, or radiological). When an ADS signal alarms, the laboratory must immediately follow procedures identified in the Response Plan and notify the pre-determined list of public health and safety agencies that will be notified. As soon as practicable, but no more than 1 hour following a signal, notify the Department or an authority designated by the department, and document the date, time, and name of responsible person contacted.

2. Timely Verification Procedures:

Identify steps that the laboratory will take to verify the presence/absence of the presumptive agent (i.e., through pre-determined confirmatory testing by an laboratory within the Laboratory Response Network (LRN) laboratory or Hazmat unit), and request results of any supplemental testing and remediation regarding a false signal.

3. Procedures to Render the ADS Inoperable:

Describe the steps that will be taken to inactivate the ADS when supplemental testing confirms that the ADS signal was inconsistent with the expected reason for the signal.

4. Emergency Shutdown Procedures:

Describe the steps that the laboratory will take to render the ADS inoperable until the cause of the discrepancy is determined, remediated, and documented through a Corrective Action Report.

**B. Evacuation**

Through the collaboration with identified responding agencies, and detailed pre-event planning, the laboratory must identify whom / on whose authority and oversight that evacuation will occur. Aspects to consider in this section include the safest route of egress, the location of a safe and designated area to send people once evacuated etc.

**C. Medical Evaluation of Staff**

Through the collaboration with identified responding agencies, and detailed pre-event planning, the laboratory must identify whom / on whose authority and oversight that the medical evaluation of exposed staff and/or building occupants will occur.

**D. Medical Treatment**

Through the collaboration with identified responding agencies, and detailed pre-event planning, the laboratory must identify whom / on whose authority and oversight that medical treatment of exposed staff will occur.

**E. Decontamination**

Through the collaboration with identified responding agencies, and detailed pre-event planning, the laboratory must identify whom / on whose authority and oversight that facility and personnel decontamination will occur.

## Section V: Procedures for Sample Handling

**A. Sample Collection:**

As documented in the Laboratory's Standard Operating Procedure Manual (SOPM), the facility must establish protocols to document the proper sample collection and labeling of a secondary sample that may be taken to a pre-designated facility for confirmatory testing. Reference existing standards such as ASTM E2601-08: 'Standard Practices for Radiological Emergency Response', and ASTM E2458-06: 'Standard Practices for Bulk Sample Collection and Swab

Sample Collection of Visible Powders Suspected of being Biothreat Agents from Non-porous Surfaces', etc.

**B. Decontamination:**

The SOPM must also identify appropriate policies and practices surrounding decontamination of the sample in accordance with the acceptance criteria of the facility receiving the sample for confirmatory testing.

**C. Packaging:**

Policies must also be identified for the appropriate packaging of the sample in accordance with the acceptance criteria of the facility receiving the sample for confirmatory testing (i.e., triple containment, enclosed in a hard-sided outer container).

**D. Transportation:**

Guidelines for the transportation of the sample to a receiving facility must be pre-identified in the Response Plan, including all ***state and federally-required Chain of Custody Procedures***.

**E. Disposal/ Destruction:**

This section must detail all policies and procedures must be clearly identified for the disposal or decontamination of the samples as appropriate for the relevant suspected agent.

**F. Containment:**

This section must detail the planned containment and Secured Storage Protocols of the samples relevant to the suspected critical agent.

***NOTE:*** *If the laboratory is* ***unable*** *to fulfill any of the above requirements (i.e., does not possess appropriate levels of Personal Protective Equipment (PPE) or collection materials) then this Response Plan must pre-identify a law enforcement and/or first responding partner whom will accept those responsibilities on behalf of the laboratory. All Chain of Custody, collection, decontamination and storage policies must be developed in consultation with law enforcement officials or other persons appropriately knowledgeable and trained to advise on these topics.*

## Section VI: Confirmatory Testing Results

**A. Reports:**

Test results must be reported in a format consistent with the reporting criteria as outlined in the SOPM, but at a minimum include the date/time/location of signal, and the suspected agent identified. As outlined in Section IV of this Response Plan, all verbal and written reports must identify these results as "Presumptive" or "Preliminary" results until confirmatory testing is performed. Confirmatory results originating from the pre-identified Laboratory (i.e., LRN)

and/or HazMat partner must be transmitted to the Department, and documented at the ADS laboratory as a confirmatory finding.

**B. Notification Procedures:**

The certified laboratory must report the Presumptive/ Preliminary laboratory ADS finding to the Department of Health (or authority designated by the department) as soon as practicable but no later than one hour, when ever findings indicate that a critical agent was detected. Notification may occur via telephone utilizing a number pre-identified by the Department or the Department's designee, documenting the date, time, and name of responsible person contacted. This Response Plan must also outline the approved policies and procedures for the timely communication between the ADS Operator and Technical Director, and between the client/ building owner (for which the laboratory is operating the ADS) and the laboratory.

**C. Records Retention:**

For each ADS in operation, the laboratory must maintain records on it's premises, including documented street address and description of physical location of the ADS. All records pertaining to ADS operating, maintenance, and response must demonstrate compliance with all federal, state, and local rules for registration, use, and disposal of materials, must be maintained for a minimum of 5 years. All access records, chain-of-custody records and records of the analyses of confirmed positive samples must be maintained for 10 years, unless otherwise determined by law enforcement to support the statute of limitations for bringing any related criminal or civil action has expired.

## Section VII: Risk Communication

Communicating effectively with the public will be essential during a positive signal to an ADS. Therefore, certified laboratories and building owners should determine which agency will be responsible for risk communication with local media and affected persons during an event. This may be an appropriate role for a county health department, or state /federal official. This section of the Response Plan should identify which agency will take lead and determine should / should not be included in the risk communication.

## Section VIII: Reoccupation

The plan should identify the state and local public health and safety partners that are responsible for coordinating and finalizing requirements for reoccupation of the building where the ADS is installed.

## Section IX: Drills and Exercises

Participation in local or state-coordinated drills and exercises are key components in ensuring that all partners outlined within this plan understand their roles following an ADS signal. It is

recommended that exercises occur both internally (outline decision-making processes, notification processes, identify pre-determined immediate actions) and externally with partnering local and state agencies at least annually.

## Section X: Annexes

Annexes may include (but are not limited to), references or copies of additional internal plans, policies, memos, bulletins, or other standard operating guides or protocols that pertain the implementation of this plan or planning partners involved in the collaboration of response. This section may include attachments regarding the ADS system operations, limits of detection and operating procedures.