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FRMAC Laboratory Analysis RadResponder Gap Analysis and Web Portal Enhancements

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Executive Summary

The Federal Radiological Monitoring and Assessment Center (FRMAC) relies on accurate and defensible analytical laboratory data to support its mission. FRMAC Laboratory Analysis personnel are responsible for (1) receiving samples, (2) managing samples, and (3) providing data quality assurance. Currently, the RadResponder software application does not meet all these needs. With some modifications, RadResponder could meet the needs for sample receiving functions, but it does not meet the needs of sample management and data quality assurance functions. The FRMAC Laboratory Analysis team has discussed and reviewed the following options moving forward:

Option 1: Make minor revisions to RadResponder to improve sample receiving capability, purchase and configure a commercial laboratory information management system (LIMS) to perform sample management and data quality assurance, and build an interface between RadResponder and the commercial-off-the-shelf LIMS.

Option 2: Make major revisions to RadResponder for all FRMAC Laboratory Analysis functions to support required sample management and data quality assurance activities.

Option 3: Create a custom-built LIMS system to interface with RadResponder.

Note: All three options will require the development of a Laboratory Analysis web portal and will require funding for ongoing maintenance and training.

The FRMAC Laboratory Analysis team highly recommends Option 1 as the best and most efficient path forward. Commercial-off-the-shelf LIMS products have been proven successful in the laboratory community for decades. Option 1 leverages these proven technologies and takes advantage of RadResponder's current strengths.

Through some recent drills conducted by FRMAC Laboratory Analysis personnel, it has been noted that RadResponder is unable to provide necessary FRMAC Laboratory Analysis functions in its current state. Recognizing this gap in the deployment of RadResponder, the FRMAC Laboratory Analysis Working Group conducted a thorough comparison of RadResponder to standard operating procedures employed at FRMAC. This evaluation took the form of several RadResponder reviews and exercises with various users and agencies. The reviews included personnel from Sandia National Laboratories, Remote Sensing Laboratory, Lawrence Livermore National Laboratory, Nevada National Security Site (NNSS), and the U.S. Environmental Protection Agency (EPA). The first session was held at Sandia National Laboratories, the second at the Remote Sensing Laboratory in Las Vegas, Nevada, and the third at the National Analytical Radiation Environmental Laboratory in Montgomery, Alabama.

This report presents the gaps that were identified and, in some cases, suggested improvements to RadResponder that would enable FRMAC Laboratory Analysis personnel to complete their mission successfully. The improvements are organized into the following categories:

- Global system attributes
- Samples
- Analysis requests
- Sample results

- Data review process
- Metrics, reports, and maps
- Multiagency data integration
- Web portal enhancements

In addition to evaluating the sample control process for RadResponder, this focus group discussed high-level requirements for transitioning the functions of the existing Laboratory Analysis web portal over to RadResponder. These requirements are described in detail in the following sections of this report.

Background

The Federal Radiological Monitoring and Assessment Center (FRMAC) relies on accurate and defensible analytical laboratory data to support its mission. Therefore, FRMAC personnel must ensure that the sample data provided by analytical service laboratories can be collected and maintained in a robust laboratory information management system (LIMS). The current system used to accomplish this endeavor is the Radiological Assessment and Monitoring System (RAMS). This web-based database is used to manage response data from FRMAC field teams and partner organizations, including field monitoring measurements, in situ gamma spectroscopy measurements, real-time telemetry equipment measurements, field samples, and analytical results. RAMS has been used as the main analytical data management tool in responses, drills, and exercises performed by FRMAC personnel for several years and has undergone continuous improvements through the Radiological Response Data Portal (formerly eFRMAC) working group.

In addition to RAMS, a parallel system known as RadResponder has been developed for use by state radiological emergency preparedness programs to manage response data. RadResponder handles much of the same data as RAMS, though it is designed in a more open and free flowing context. RadResponder essentially allows users to work with the system in the way they see fit rather than conforming to a set of data standards as they do with RAMS. This flexible design concept enables organizations to adopt RadResponder more easily by requiring fewer process changes to established standard operating procedures. However, these open data requirements can lend themselves to questionable data quality and consistency across organizations and events. These concerns are magnified when more complicated data is encountered in in-situ gamma spectroscopy and laboratory analysis results.

To date, neither RadResponder nor RAMS meet all the needs for FRMAC Laboratory Analysis. The following report attempts to identify the major gaps in RadResponder capabilities and then propose solutions to these problems for consideration by development teams.

List of Acronyms

AAL	analytical action level
ARF	Analysis Request Form
DVF	Data Verification Form
EDD	electronic data deliverable
EPA	U.S. Environmental Protection Agency
FRMAC	Federal Radiological Monitoring and Assessment Center
ICLN	Integrated Consortium of Laboratory Networks
L_c	critical level
LIMS	laboratory information management system
MDE	minimum data element set of the ICLN
NCF	Non-Conformance Form
QA	quality assurance
QC	quality control
RAMS	Radiological Assessment and Monitoring System
SCF	Sample Control Form

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RadResponder Gap Analysis and Recommended Improvements

1 Global System Attributes

1.1 Sitewide

1.1.1 The security feature that logs users off after a period of inactivity may cause some inefficiencies.
Suggested Improvement: Increase the time limit before computer lockout or remove the lockout feature altogether.

1.1.2 The system lacks on-the-fly data entry validation.
Suggested Improvement: Create a feature to flag users or turn text red if something is entered in the wrong format.

1.1.3 There is no ability to initiate a Non-Conformance Form (NCF) to track problems with samples, Analysis Request Forms (ARFs), and analytical results.
Suggested Improvement: Develop an NCF. The NCF must:

- be tracked uniquely in the system
- be categorized as an issue with a sample, an issue with an ARF, or an issue with a sample result(s)
- be tagged to all the data elements (samples, ARFs, and results) and be accessible in the view when looking at those elements
- track who initiated the NCF, what the issue was, who corrected the issue, what was done to correct the issue, and what the date and time was when the NCF was initiated
- have a view or dashboard that can be used to monitor NCFs and to open, edit, and resolve them
- have the ability to initiate, resolve, or have more than one NCF associated per sample or per ARF

1.1.4 Individuals who enter data in the system for their laboratory can also view event data and sample location information from other laboratories, and can edit other data in the system. This is an information security issue for FRMAC. There should be controls that allow various laboratory personnel to enter data without having these additional permissions.
Suggested Improvement: Build a laboratory data entry portal into RadResponder. **Note:** The requirements for such a system are described in "Laboratory Analysis Web Portal Enhancements."

1.2 System Roles and Privileges

1.2.1 There is no way to censor unreviewed data from users. This can lead to incorrect data products or improper decisions by stakeholders. FRMAC Laboratory Analysis and Assessment personnel have data quality assurance (QA) and quality control (QC) review responsibilities to carry out during a response. In its current state, RadResponder does not support these activities.
Suggested Improvements: Add data review fields and levels of permissions to support implementation of current FRMAC Laboratory Analysis and Assessment QA/QC procedures. Define a new permission set called "FRMAC Assessor" that defines access to new QA review fields described in this document.

1.2.2 RadResponder users lack the privileges necessary to manage events for drills and exercises.
Suggested Improvement: Grant privileges to all Laboratory Analysis leadership (Laboratory Analysis manager down to Consequence Management Home Team members) needed to create an event for training and drills.

1.2.3 Normal RadResponder users lack the privileges necessary to validate data.
Suggested Improvement: Add the role of Data Assessor as a default setting in addition to Data Collector and Data Viewer for Laboratory Analysis personnel. This role is likely needed for QA/QC review at any level, and should be added even if the FRMAC permissions are also created to support state and other parties' QA/QC processes.

1.2.4 Personnel with Event Manager privileges lack the ability to upload result data.
Suggested Improvement: Provide the Event Manager with the ability to upload data (as part of the response itself, not just injecting drill data).

1.2.5 Assigning privileges to users is cumbersome.
Suggested Improvement: When selecting privileges for users, set the checkboxes to autofill with all the inherited roles associated with that privilege.

1.3 Event Setup

1.3.1 Too many time zone entry variations are allowed, which causes problems communicating sample collection data to analytical laboratories for decay correction.
Suggested Improvement: Standardize time zone entries.

1.3.2 There is no way to specify more than one laboratory point of contact.
Suggested Improvement: Create the ability to manage multiple laboratory points of contact for an event. This will provide users with a picklist of contacts to use in the ARF.

1.3.3 Users must request a change to a laboratory record from Chainbridge, which means someone must be on call for all drills or training and testing events.
Suggested Improvement: Add the ability to add or edit a laboratory record as well as to assign one to an event.

1.3.4 Analysis methods are hard-coded into the system; however, these methods sometimes change over time.
Suggested Improvement: Add the ability to edit or add analysis methods to the available picklist.

1.3.5 When working on the Event Creation screen, there is no information to describe what "Sharing Mode" is.
Suggested Improvement: Add an information box describing the Sharing Mode field.

1.3.6 The Wind Direction information box on the Event Creation screen does not indicate the time at which the information is valid.
Suggested Improvement: Set up the information box to indicate that wind direction is at the time of release.

1.3.7 There is no information to describe what "Partners Only" means.
Suggested Improvement: Add an information box to explain the "Partners Only" feature.

1.3.8 The Event Summary page does not show the event address or latitude and longitude.

Suggested Improvement: Add address and latitude and longitude information on the Event Summary page.

1.3.9 It is unclear what a "Private" event is.
Suggested Improvement: Add an information box to define the Private event option.

1.3.10 There is no way to specify a mailing address for samples that need to be returned to FRMAC.
Suggested Improvement: Add the ability to specify a mailing address for returning samples to FRMAC on the Event Creation page.

1.3.11 The data upload template is somewhat hard to find.
Suggested Improvement: Place a copy of the data upload template in the Documents section so that it can be sent to laboratories with the ARF documents.

1.3.12 The collection agency is not identified during an event merge.
Suggested Improvement: Add a Collection Agency field on all data types to be captured during import operations.

1.3.13 The system does not record what original events were used to merge data together, which may lead to data conflicts if the two events have the same sample IDs or ARF names.
Suggested Improvement: Create a new name or sample IDs and ARF names that are duplicated with a discriminating identifier (e.g., add a "-1"). Either indicate the newer sample/ARF as the duplicate *OR* designate one event as the "host" event and any samples or ARFs added from the other event as duplicates.

1.4 Job Aids

1.4.1 The Laboratory Analysis job aids are somewhat lengthy and need to be more searchable.
Suggested Improvement: Add a table of contents to the Laboratory Analysis job aids or publish more simplified one- to two-page job aids.

1.4.2 Laboratory Analysis staff sometimes collect samples, but this task was not included in a Laboratory Analysis job aid.
Suggested Improvement: Create job aid for collecting samples and place a copy of it or a link it with the other Laboratory Analysis job aids.

1.4.3 There is no job aid for creating an event. (The video is informative and nice to have.)
Suggested Improvement: Create a job aid for setting up an event.

1.4.4 There is no clear understanding of how RadResponder will be failed-over and backed up in the field. If internet providers go down (which is likely to occur during a large event), operations personnel must continue to use the local network infrastructure and telemeter to the cloud servers for offsite use.

1.4.5 The "X" button used for saving Date entries was confusing to most users. The "X" leads users to think that selecting it will ignore changes.
Suggested Improvement: Change the "X" button in Date entry boxes to a checkmark.

1.4.6 There is no way to bulk import measurements, sample records, ARFs, and analytical results for the purposes of drills and exercises. This is a necessity when exercising the latter stage of an incident when there is a great deal of information in the system. Entering this inject data by hand could take weeks to accomplish.

Suggested Improvement: Develop a standard format for the bulk upload of sample records, ARFs, and analytical results for drills and exercises.

1.5 Mixtures

1.5.1 The description of analytical action level (AAL) ratios needs to be clearer; users were confused by the wording.
Suggested Improvement: Change the wording to: "Action levels are multiplied by [this value] to determine the required critical level."

1.5.2 Some cases require the analysis method of "Other" to be specified.
Suggested Improvement: Add the ability to specify "Other" as the analysis method for an analyte on a mixture.

1.5.3 The system does not have default AALs stored in the system.
Suggested Improvement: Store default AALs based on scenario- and matrix-based input from FRMAC Assessment and Laboratory Analysis. These values should auto populate if the user presses a button in mixture creation.

Note: Laboratory Analysis and Assessment personnel are currently working on generating these tables.

1.5.4 There is no way to import electronic AAL or critical level (L_c) values for nuclides; hand entry is required for each individual number.
Suggested Improvement: Add the ability to electronically import an analyte AAL or L_c list generated from Turbo FRMAC.

1.5.5 It is unclear that when finalizing a mixture, users can copy an existing mixture if edits need to be made.
Suggested Improvement: Add more verbiage on the screen about finalizing a mixture. For example, point out other available options such as Copy.

1.5.6 Applicable AAL/L_c values are unknown in several cases. In these cases, FRMAC Laboratory Analysis personnel will specify a count time that labs are to use when analyzing samples. RadResponder does not currently allow for this to be done in a mixture.
Suggested Improvement: Add a way to specify count times when Laboratory Analysis personnel do not have applicable AAL/L_c values to work with. Require this for the mixture and then propagate to the ARF and ARF PDF so that labs personnel receive this information. Ensure that the user can toggle the specific L_c or count time by matrix as this may vary within a mixture.

1.5.7 When AAL/L_c values are provided to lab personnel that cannot be meet in a reasonable amount of time, FRMAC Laboratory Analysis personnel will specify a maximum count time to use. RadResponder does not currently have a way to communicate this to the laboratories points of contact.
Suggested Improvement: Add a field on the mixture for "Maximum Count Time" that will be used if L_c cannot be met. Have this print on all ARFs, using this mixture on the front page next to the special instructions.

1.5.8 Some options for analysis method are confusing. On the pull-down tab to select an analysis method, both "Gamma Isotopic" and "Gamma Spectroscopy" are specified as selectable options; this is redundant.
Suggested Improvement: Remove Gamma Isotopic as an optional analysis method.

1.5.9 There is no easy way to manage the picklist for an analysis method; changes to the list require Chainbridge to be contacted.
Suggested Improvement: Provide Laboratory Analysis personnel with the ability to manage the picklist for analysis method or with an easy process to request a user interface.

1.5.10 Swipe is not listed as a matrix in the table. While Laboratory Analysis personnel may not specify L_c values, they will specify count times.
Suggested Improvement: Modify the system to allow entry of L_c and count times for all possible matrices available (including in situ measurements). Set up the mixture table to show all matrices selected as active for the event.

1.6 Field Teams

1.6.1 When a team member is added to the field team list, the phone number is prepopulated. However, some auto populated phone numbers are stored in an incompatible format, requiring users to click in the box, then click out of the box, so the field will autocorrect.
Suggested Improvement: Design the system to evaluate and correct auto-imported data.

1.6.2 The "Chat with Team" button does not do anything when clicked on in the web app or in the mobile app. This would be a very nice feature for Laboratory Analysis personnel, as it would enable efficient communications between sample control and hotline personnel, who are often physically separated by some distance.
Suggested Improvement: Fix this tool and then communicate its function to the user community.

1.7 Data Collection Set

1.7.1 The data collection set only allows users to predefine data collection templates for field teams; it does not tie all the data collected under a set together in any way. The sample collection set is a very powerful feature that could improve the consistency of operations if implemented properly.
Suggested Improvement: Add a unique ID to the set to make data queries more powerful for Laboratory Assessment scientists when they are trying to get a view of all available data for an area. Note: Have the FRMAC working groups discuss this during an upcoming interdivisional meeting to see whether Monitoring and Sampling and Assessment personnel would like sets to be tracked together under a unique ID system. Provide specifications for such a tracking scheme after this meeting occurs.

1.7.2 The map display does not show the event ground zero and the user's current location.
Suggested Improvement: Modify the map to show the event ground zero and the user's current location.

1.7.3 There is no way to tie a sample, ARF, or results to a Request for Information or other mission-tracking data element. This presents problems in being able to control workflow in an event and in communicating priorities or a set of data's purposes.

Suggested Improvement: Add a new data element (which would eventually tie to the future CM workflow management software) to contain information linking the data set to the mission being carried out. Allow priorities to be tracked by mission rather than by individual samples, which is much easier to manage.

1.7.4 There is no way to save a data collection set during collection. For larger sets, this may present a problem if connectivity is lost.
Suggested Improvement: Modify the system to allow users to save a data set with incomplete actions to avoid loss of critical data if an internet or machine power outage occurs.

2 Samples

2.1 Sample Data Element

2.1.1 There is no way to associate a nonconformance with a sample record.
Suggested Improvement: Add the ability to attach a nonconformance to its associated sample. (See item 1.1.3.)

2.1.2 There is no way to associate what ARF(s) a sample is attached to.
Suggested Improvement: Add a field to the sample view to indicate what ARF(s) a sample is attached to.

2.1.3 There is no way to determine what agency collected a sample when events are merged or data is imported from other systems.
Suggested Improvement: Create a new field to indicate the agency responsible for the collection of the sample.

2.1.4 There is no easy way to tell the time zone for the collection date on a sample. There is also no way of indicating the correct time or time zone when a user is in one-time zone while remote connected to a computer in another time zone.
Suggested Improvement: Indicate the time zone on all displayed time fields. Alternatively, allow all times to be displayed in Coordinated Universal Time.

2.1.5 There is no way to associate electronic signatures to the various RadResponder reports, including the sample control form. FRMAC Laboratory Analysis personnel print forms for signature and recordkeeping purposes.
Suggested Improvement: Allow electronic signatures for documents such as Sample Control Forms (SCFs), NCFs, and ARFs. Have the SCF auto populate the signature of the sample collector and the receiving staff at the hotline. Have the ARF auto populate the signature of the staff who clicks the shipped button. Have the NCF auto populate the signature of the initiator and resolver.

2.1.6 There is limited ability to recover sample collection data during offline operations. Laboratory Analysis personnel must retain the ability to process samples even if the system is down.
Suggested Improvement: For the tablets, have the system create a PDF of the SCF, drop the form into a temporary folder, and then save the form on the local storage drive so it can be recovered if the whole system goes down and there is a need to fall back on a paper sample tracking process.

2.1.7 There is no system to track priority of samples.
Suggested Improvement: Add a field that users can toggle on or off to indicate high priority for samples. Have the system flag high-priority samples as red on all views to catch the user's eye. Have the system flag high-priority ARFs as red both on screen and on the PDF report. When a command and control system is employed in FRMAC, update RadResponder to support the workflow and prioritization scheme of that system.

2.1.8 There is no ability to upload files to a sample record in addition to the image file.
Suggested Improvement: Allow users to enter a comment on a file to describe what it is. Have the system track when the file was uploaded and by whom. Allow users to tag other data

elements to the file, such as SCFs or ARFs. Have the List View display this information for all attached samples including analysis result reporting.

2.1.9 In situ measurements do not get a unique identification number assigned or have a status in the system. An FRMAC gamma spectroscopist cannot perform the analysis and enter results for the measurements.
Suggested Improvement: Track in situ measurements like samples (apart from needing to use an ARF for results to be uploaded). Provide a sample ID, allow for the import of a spectrum file and other ancillary documents, and allow results to be entered in the same format as sample results. Provide the same data review process for in situ measurements as for sample results, and have a data verification form associated with reviewed results.

2.2 Sample Collection and Data Entry

2.2.1 There is no way to retrieve the next available sample ID when creating a new sample. The system should prevent the creation of duplicate sample ID numbers.
Suggested Improvement: Develop a button to autogenerate the next available sample number and place it in the correct field when creating a sample.

2.2.2 It is unclear where the sample import template file is on the screen.
Suggested Improvement: Place the *s*ample import template in a more intuitive location, and rename the button "Sample Import Template."

2.2.3 There is no ability to reprint sample barcode labels for sample numbers that are already used. This is needed when numbers were used in the field with no printer available, when labels are damaged and need replacement, or when samples come in from outside agencies with no labels or incompatible formatted labels.
Suggested Improvement: Instruct users to enter the numbers for the required label, indicate the requested number of copies, and print.

2.3 Sample Status Tracking

2.3.1 Laboratory Analysis personnel needs more robust workflow management tools to support sample tracking and monitoring sample status.
Suggested Improvement: Add a few key steps to the sample status scheme.

2.3.1.1 For sample status (the physical location of a sample), add the following conditions:

- **Collected** – Autogenerate when a sample is first created in the system via web interface or tablet application. Indicate that the sample has not yet been delivered to the hotline.
- **Received** – Trigger by a sample control specialist at the hotline when samples arrive and are checked for consistency and packaging/collection practice compliance. **Note:** Create a utility that makes this manual status update as easy as possible when several samples show up at the hotline at once. Consider the use of barcode scanners to set the status of samples in bulk.
- **Hold** – Indicate that something is wrong with the sample and that it is being put aside. Auto populate when an NCF is initiated and tagged to the sample. When the NCF is resolved, have the system ask the user what next status the sample should get (choices should be: Received or Not Usable).

- **Not Usable** –Trigger through the resolution of an NCF. Indicate that a sample will not be carried through the process. Store these not usable samples in a special location so they can be addressed later.
- **Sent to Lab** – Auto populate when a sample is attached to an ARF that has had the "Ship" button pressed. Indicate that a sample has left the custody of FRMAC and is now either on its way to the lab or at the lab.
- **Disposed** – Indicate that a sample has been disposed of; this is a manual promotion from any of the statuses above. **Note:** Create a utility to update this status in bulk using a barcode scanner or manual entry.

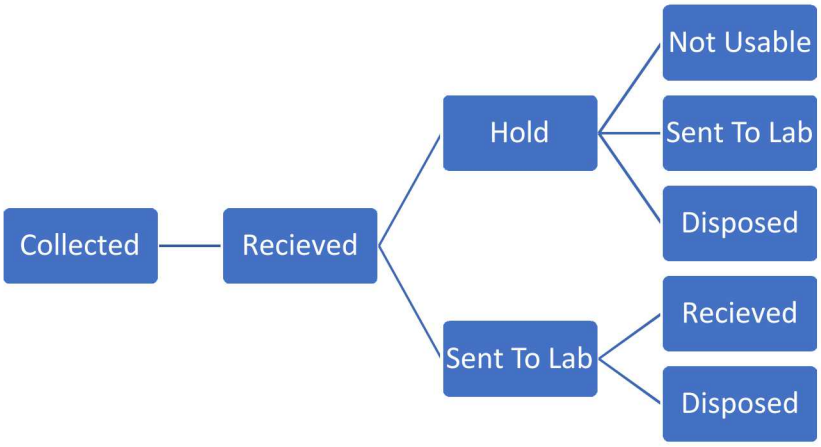

Figure 1. Sample status lifecycle

2.3.2 Laboratory Analysis personnel need a way to track sample locations in addition to a sample's physical status.
Suggested Improvement: Options should be:

End Route – Auto trigger when a sample is created. **Note:** Ensure that the shipment tracking number field on the ARF is viewable on the sample table
Storage – Auto trigger when a sample is promoted from Collected to Received.
Laboratory Name – Auto populate with the name of the laboratory the ARF is associated with and that the sample is attached to. For samples attached to multiple ARFs, have this reflect the laboratory with the latest shipment date.
Disposed Of – Auto trigger when a sample status is set to "Disposed Of."

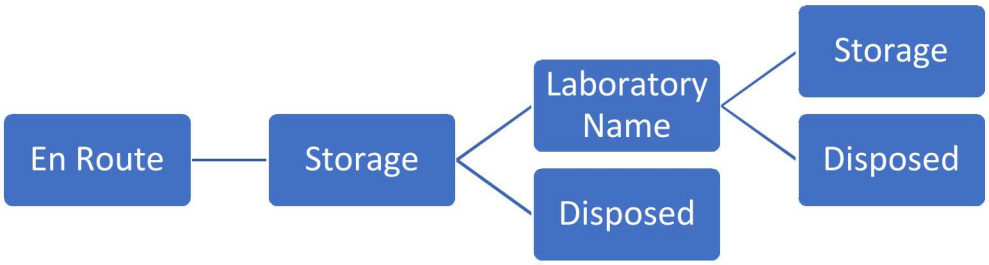

Figure 2. Sample location Lifecycle

3 Analysis Requests

3.1 Analysis Request Form Data Element

3.1.1 Labs personnel are confused when several required critical levels reported for the list of analytes are apparently conflicting. Data quality objectives such as the list of radionuclides requested, the required L_c for each, alternatively the minimum count time for each, and maximum count time should L_c not be met for each are important to communicate clearly and consistently on the ARF document. FRMAC Laboratory Analysis personnel ask labs personnel to analyze to the "most restrictive" L_c, which is often impossible. Thus, FRMAC Laboratory Analysis personnel sometimes must anchor the analysis of the entire sample to the L_c of a single nuclide that is most important to the data user or is the best the analysis lab personnel can do under the circumstances.
Suggested Improvement: On the ARF or the mixture, allow this to be done in a user-friendly way. On the ARF, make it clear to labs personnel what individual L_c they are requested to perform the analysis to.

3.1.2 There is no place to record an analyte-specific comment on the ARF.
Suggested Improvement: Add a field to the analyte table for an analyte-specific comment. Import the default from the mixture table, and allow editing of the comment at ARF level.

3.1.3 The ARF is unable to communicate the count time if there are no AALs entered in the mixture.
Suggested Improvement: Have the system indicate a default count time when no AAL is listed, either adding a setup at the mixture level or allowing a detection level to be added manually.

3.1.4 Some of the fields on the ARF are confusing to users.
Suggested Improvement: Rename the "Return to:" field on the ARF as "FRMAC Point of Contact." Have the form use the address of the stood-up FRMAC configured at the event level. Ensure the names are editable, but have the form retain the FRMAC address.

3.1.5 There is no way to associate a nonconformance form with an ARF.
Suggested Improvement: Modify the system to allow NCFs, one or more, to be associated with samples, ARFs, and analytical results. (See specifications for NCFs in item 1.1.3.)

3.1.6 There is no way to upload and attach documents to an ARF that relate to the sample results submitted by the laboratory. Users must be able to upload several large documents (note the maximum size for an attachment on the web page) to the ARF that include analytical reports and case narratives from the lab for the batch of samples.
Suggested Improvement: Allow users to enter a comment describing each file, record who uploaded the file and when, and allow users to tag which samples are associated with the file. Have the links to these documents display on the ARF view and in the individual sample views. Allow FRMAC users or laboratories personnel to upload files through their portal (see requirements in the Laboratory Analysis Webportal Enhancements section of this document).

3.1.7 There is no way to specify a turnaround time requirement on the ARF. This is needed to communicate to labs personnel and should be printed on the ARF document.
Suggested Improvement: Add a field to the ARF data element to specify the turnaround time requirements for the analysis.

3.2 Analysis Request Form Creation

3.2.1 There is no way to generate a unique ARF number when creating a new ARF.
Suggested Improvement: Create a button to autogenerate a unique ARF ID number. Also allow manual entry of an ARF number from a paper logbook and check for uniqueness. Suggested format: [current date]-### counting from 001 for the event.

3.2.2 The analysis contact must be entered manually at ARF creation; however, the staff creating the ARF may not have this information.
Suggested Improvement: Have the Event Analysis contact auto populate from the event when an ARF is saved.

3.2.3 When attempting to attach a sample to an ARF that already exists on another ARF, the system does not warn the user. This will lead to attaching incorrect samples to ARFs.
Suggested Improvement: Have the system warn users when attempting to do this, but do not have the system forbid it as it is sometimes necessary. Display all associated ARFs on the sample view.

3.2.4 When data quality objectives are changed on an ARF from the values determined by the mixture used, the system does not record that something was changed, thus breaking traceability back to the mixture settings.
Suggested Improvement: If the DQOs (requested analytes [nuclides] or their L_c values or units) are changed for an ARF, have the field capturing the mixture used for the ARF toggle to "CUSTOM" to show that edits were made. If no changes are made, have the system retain the original mixture chosen.

3.2.5 When an ARF is marked as Complete and Shipped, edits to the ARF can still be made, which leads to discrepancies between what is in RadResponder and what labs personnel receive.
Suggested Improvement: Do not allow changes to be made to a shipped ARF. In cases where changes must be made, require that an NCF be initiated to describe the changes and how they were communicated to labs personnel. Ensure that this is accessible on the ARF record as well as all on the samples attached to the ARF.

3.3 Analysis Request Form Status Tracking

3.3.1 ARF status tracking is insufficient in RadResponder and will make it difficult to provide timely and accurate information, sample and result status, and situational awareness to leadership.
Suggested Improvement: Trace ARF status in the system in the following way:

- **Created –** Auto trigger when ARF is first saved.
- **Sent to Lab** – Trigger when the "Ship" button is pressed on the ARF but no results have been uploaded for any of the requested analytes yet.
- **Unreviewed Results** – First trigger when results are uploaded to the system that have not yet been marked as reviewed (when data is available to review). When all results that have been uploaded are reviewed, have the status toggle to Complete. When new results are entered, have the status switch back to Unreviewed Results.

- **Complete** – First trigger when all uploaded results are marked as reviewed. Have the status cycle back to Unreviewed Results when new results show up in the system that are not yet reviewed. Have the final state be Complete when all results are reported and reviewed.

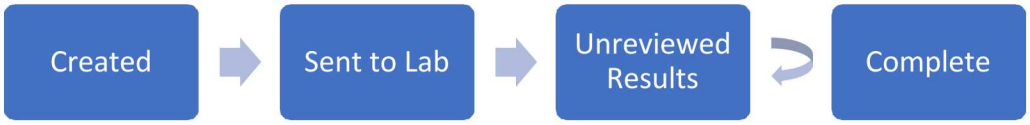

Figure 3. Analysis request form status lifecycle

Note: *Status cycles between unreviewed results and complete as results are uploaded for an ARF.*

3.4 Analysis Request Form Document

3.4.1 The comments typed in the ARF screen are not printed onto the ARF.
Suggested Improvement: Have one clear "Special Instructions" open text box that can be filled in with predefined verbiage set up on the mixture *OR* manually edited ARF by ARF. Have this print on the first page of the ARF.

3.4.2 The Sample Comment is printed over and over on the ARF document.
Suggested Improvement: Have the Sample Comment field on ARF documents print on the sample information header, not analyte by analyte since it is a property of the sample and not the analyte.

1.1.1 There is no ability to scan the ARF name and sample IDs into the LIMS via barcode scanner.
Suggested Improvement: Render the ARF name as a barcode on the ARF document. Have barcodes for each sample print on the last page of the ARF so laboratories personnel can scan the sample IDs directly into their LIMs.

3.4.3 There is no way to tell what the time zone is for dates and times printed on the ARF document.
Suggested Improvement: Have the sample collection date and time on the ARF document print the time zone.

3.4.4 If pages of the ARF document get mixed up, there is no way to determine the correct order.
Suggested Improvement: Have the ARF number print on each page, and add page numbers x of y.

3.4.5 There is no way to create an ARF if the system is down.
Suggested Improvement: Create a blank ARF for downloading and printing so users can enter sample information manually when the system is down.

3.4.6 There is some confusion on some of the ARF document fields.
Suggested Improvement: Change "Barcode" to "Sample ID" on the ARF document. Change "Nuclide" to "Requested Analyte" on the ARF document.

3.4.7 There is no way to tell what the sample matrix is on the ARF document.

Suggested Improvement: Include the sample matrix on the ARF document.

3.4.8 There is no way to track chain of custody using the RadResponder ARF document. Sample Control Forms are *NOT* sent to laboratories personnel to protect the sample location information. When attached to an ARF, the chain of custody is tracked for the entire batch of samples on that form.
Suggested Improvement: Add a page to the ARF for signature lines, which will be used for chain of custody operations. Consider using electronic signatures to reduce the need for printing.

4 Sample Results

4.1 Sample Result Data Element

4.1.1 Numbers are displayed in inconsistent formats site-wide.
Suggested Improvement: Only display numerical fields on sample result records in scientific notation site-wide.

4.1.2 There is some confusion with the fields used for sample results.
Suggested Improvement: Rename Result Date to "Reference Date and Time." Modify the field description to say: "This is the date to which the result has been decay corrected." Or "This is the reference date for the analytical result." Also, change "Reported by" to "Reporting Agency." Have the field capture the organization represented, not an individual.

4.1.3 RadResponder does not require a sample be attached to an ARF to upload results; however, this requirement is necessary so that samples, analysis, and results can be tracked accurately through the process. Being able to track status is key to providing stakeholders situational awareness during a response.
Suggested Improvement: Make an analysis request field mandatory to allow for consistent data integrity.

4.1.4 Many of the descriptions of sample result fields in the EDD template are vague and may lead to confusion.
Suggested Improvement: Reword field descriptions as indicated in Appendix I.

4.2 Sample Result Creation and Import

4.2.1 RadResponder cannot import the Integrated Consortium of Laboratory Networks (ICLN) minimum data element (MDE) set.
Suggested Improvement: Create the ability to read in the ICLN MDE set, creating sample records and results for the data to obtain information form the nation's laboratory networks.

4.2.2 Users are confused about how to obtain the EDD upload template.
Suggested Improvement: Make the EDD upload template downloadable before pressing the Import button.

4.2.3 Importing electronic results for laboratory QC samples leads to a bottleneck in data reporting and a general confusion by most laboratories supporting a response.
Suggested Improvement: Do not upload laboratory QC sample data to the database as sample results. Do this via reports uploaded as .PDF files.

4.2.4 Analytical results reported by laboratory personnel must be calculated using the wet mass of the sample (or mass as received).
Suggested Improvement: Place these instructions on the ARF.

4.2.5 Allowable units listed in the EDD template include units that are not applicable to sample results (dose, for example), which may lead to some confusion in data reporting.
Suggested Improvement: Only include units of radioactivity per sample size in the template.

4.2.6 It is unclear how duplicate result imports are handled in the system. Users do not know how RadResponder handles a case when results for the same sample, ARF, method, and nuclide need

to be uploaded to the system. Duplicate results are discriminated against one another using the data upload date. By default, results with the newest upload date show up in queries, and older results are hidden unless specifically requested in the search.
Suggested Improvement: Set the bulk sample result import tool to allow users to choose to replace an existing duplicate result (*duplicate* is defined as having the same sample ID, ARF ID, requested analyte, and reported analysis method) or append to the exiting result. Also, allow only one result to have a status of "Approved"; give the other result a status of "Superseded."

4.2.7 Filling out the EDD prior to upload can be a very time-consuming and error-prone process.
Suggested Improvement: Have the Excel EDD template provide real-time data cell validation. For example, if an incorrect nuclide name was used, the cell would turn red. Or when choosing an analysis method, have a drop-down appear.

4.2.8 The Excel EDD template may be difficult for some LIMS to produce.
Suggested Improvement: Create an additional format with the same look and requirements in a simple .CSV format to allow for more LIMS integration.

4.3 Sample Result Status Tracking

4.3.1 The system needs to track Sample Result Review Status. This is what triggers the filter for data results users.
Suggested Improvement: By default, users should only see data that is flagged as "Approved."

- **Not Reviewed** – Auto trigger when a result is uploaded to the database.
- **Accepted** – Trigger through a data review utility (described in the next section) in bulk for a set of results.
- **Estimated** – Trigger through a data review utility (described in next section) in bulk for a set of results.
- **Rejected** – Trigger through data review utility (described in next section) in bulk for a set of results.
- **Superseded** – Trigger when a result for the same sample – nuclide – analysis method is reported. The original result is given this status, and the new result is given one of the three previous statuses.

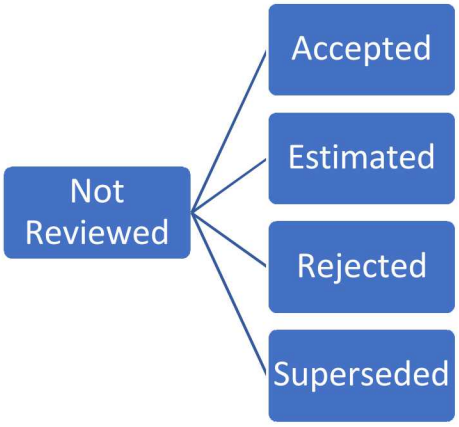

Figure 4. Sample result review status lifecycle

Note: Superseded status is reserved for results that have a more up-to-date version uploaded.

5 Data Review Process

5.1 General Comments

5.1.1 There is not a method to hide unreviewed data and restrict its use by data users.
Suggested Improvement: Create an FRMAC Accept/Reject button for sample results to include in situ data. Have the default data filter only show accepted results, so that users must toggle this off manually to see unapproved data, thus preventing users from seeing unreviewed data. Have the FRMAC Assessor govern use of this utility.

5.2 Data Review Process Description

5.2.1 The current system throws all the data into one giant table, which makes data review cumbersome and inefficient.
Suggested Improvement: Conduct data reviews on an ARF by ARF basis. This assumes data has just been uploaded by laboratory personnel including the scanned report documents and they are available on the ARF record. **Note:** Allow users to save partial reviews so that they can return and complete reviews later. This process can take some time to complete. Implement the following process for data review:

- Access the ARF record through a view that shows the ARF status as "Unreviewed Results."
- Scroll down to a new section, "Result Review."
- Open the attached documents the labs personnel provided, including the case narrative.
- Confirm the electronic data is complete and correct, review laboratory records, decide on the result status of the reported results: Accepted, Estimated, Rejected, and Superseded.
- When the utility selects all unreviewed results by default, deselect results that will have a different status or review comment.
    - If **Accepted** is chosen, no review comment is needed
    - If **Estimated** or **Rejected** is chosen, a review comment is required (this may be a new field on the result record). **Note:** This text is applied to **ALL** selected records.
    - Press Save to apply the review status and the comment to **All** selected records.
- Continue this process until all results are reviewed.
- During the process, log review comments on the Data Verification Form (DVF). Complete one DVF for each ARF. To do so, click the "Data Verification Form" button. When the stock FRMAC Data Verification Form displays, type in review comments in each section.
- Save the form or complete the form. **Note:** Upon completing the form, the system attaches the user's name as the reviewer of the ARF and applies their electronic signature to the DVF.
- **Note:** The system propagates completed forms as attached documents to the sample records that are attached to the ARF.

6 Metrics, Reports, and Maps

6.1 Laboratory Analysis Data Metrics

6.1.1 There is a lack of sample metrics that can be obtained easily from RadResponder.
Suggested Improvement: Have the system generate the following Laboratory Analysis metrics:

- 6.1.1.1 Tally samples by day they were collected
- 6.1.1.2 Tally samples by status
- 6.1.1.3 Tally ARFs by status
- 6.1.1.4 Tally sample results by status
- 6.1.1.5 Tally samples by the laboratory where they are located
- 6.1.1.6 List of ARFs at each laboratory

6.1.2 There is a lack of laboratory metrics that can be obtained easily from RadResponder.
Suggested Improvement: Display data with a bar chart by lab, showing one split bar (see Figure 5). One split shows samples completed, the other split shows samples in progress, and the sum of the bars is the total samples sent to a lab. The percentage completed should be calculated and displayed above the bar. Toggle between samples and ARFs as an event gets older and more samples are sent to labs.

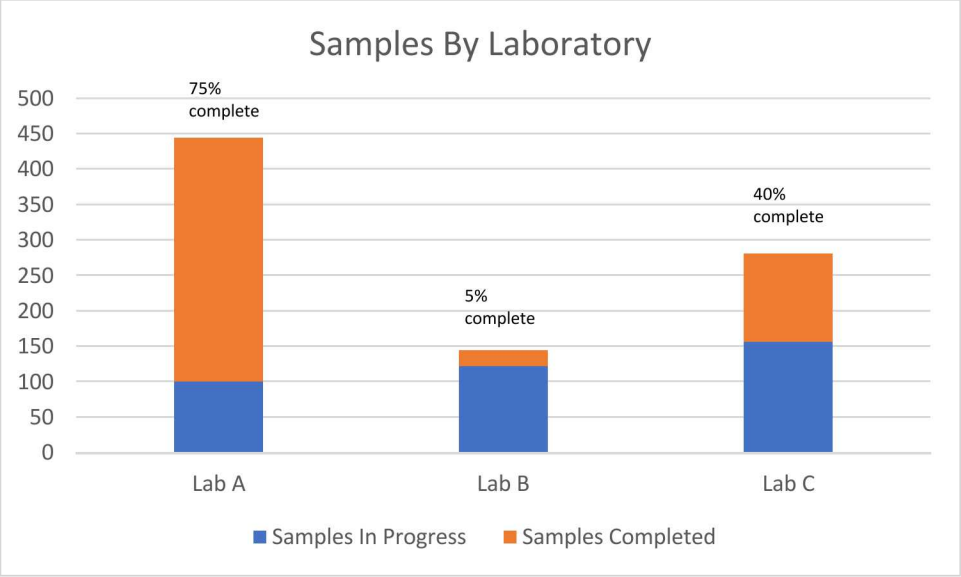

Figure 5. Example laboratory sample status

6.2 Laboratory Analysis Reports

6.2.1 There is no ability to export results in the ICLN MDE set given a set of query parameters.
Suggested Improvement: Develop a tool to specify a set of filters and export sample result data in the ICLN MDE format.

6.2.2 There is a lack of ability to export information given a time and space window.
Suggested Improvement: Develop the ability to export all data into a file given a time and space window. Include each type of data (e.g., measurement, eCAM, in situ, or sample results) on a separate tab. Export all location and time information needs to export with the data.

6.3 Improvements to Map Application

6.3.1 There is a lack of ability to show results on a map layer.
Suggested Improvement: Add the ability to show heat-mapped (color scale) results by nuclide, with filters for sample type and collection window.

6.3.2 There is a lack of ability to show samples on a map layer.
Suggested Improvement: Add the ability to show samples by type and where they were collected.

6.3.3 There is a lack of ability to evaluate analytical action levels using a map.
Suggested Improvement: Add the ability to load in a set of AALs for radionuclides that are used at threshold values to flag sample results that exceed them.

6.3.4 There is a lack of ability to indicate priority samples and their results. Also, there is no way to highlight priority sample results on export.
Suggested Improvement: Highlight priority samples and their results in some way.

6.3.5 There is a lack of ability to retrieve sample results from the map utility in a user-friendly way.
Suggested Improvement: Draw a polygon on a filtered map, and export all result records in Excel table.

Laboratory Analysis Web Portal Enhancements

Discussions held during walk down meetings made it clear that there is a need to have a FRMAC Laboratory Analysis web portal that would allow various laboratory personnel to interface with RadResponder. This creates efficiencies in data entry and reduces transcription errors by shifting the workload from the FRMAC responders to the laboratories themselves, where personnel are more familiar with the data and have more staff available for such work. Through interviews and feedback from RadResponder and Laboratory Analysis web portal users, the following list of key requirements was created for future development of RadResponder that would allow for more efficient interaction during a response:

- The system must allow laboratories personnel to access the data portal through a password-protected web application and not require any software to be downloaded.
- The system must only show laboratories the analysis request that have been sent to them for analysis.
- The system must not disclose sensitive information about samples, such as who collected it or where it was collected.
- The system must have a way for laboratories personnel to manage access to a data entry portal for their own staff.
- The system must allow laboratories personnel to manage their relevant information, including but not limited to point of contact information, shipping address information, and capabilities.
- The system must provide relevant analysis request and sample information in a standardized data format that laboratories personnel can read into their LIMS.
- The system must allow laboratories personnel to communicate shipment status and any issues involving shipping with the FRMAC.
- The system must allow laboratories personnel to enter electronic analytical results for samples and attach any relevant reports as document files.
- The system must allow laboratories personnel to upload results via standardized format file such as .CSV so that they may configure their LIMS to produce such a file.

Documents and References Reviewed

- RadResponder Lab Analysis job aids
- RadResponder Roles and Privileges table
- RadResponder event creation video
- Notes from RadResponder evaluation at Sandia National Laboratories on June 21, 2018
- Notes from RadResponder drill at the Remote Sensing Laboratory on June 27, 2018
- Notes from RadResponder evaluation at EPA on July 12, 2018
- Notes from RadResponder evaluation with EPA (phone) on August 13, 2018
- Notes from RadResponder evaluation project close-out meeting on September 11, 2018

Appendix I. Suggested RadResponder Electronic Data Deliverable Field Descriptions

RadResponder Field	Description to use in template
Result Date*	The Result Date is the date and time (in UTC) for which the results have been decay corrected to. If no decay correction has been applied, this is the date and time when the counting period started.
Reported By*	Reported By is the name of the individual who created the electronic data entry.
Sample Barcode/#*	The Sample Barcode/# is the RadResponder sample ID number as written on the ARF and any sample labels provided.
Lab/LIMS #	The Lab/LIMS # is the internal laboratory sample ID number used to identify the sample in the laboratory.
Analysis Request Name	The Analysis Request Name is the identification of the ARF provided.
Laboratory Name	The Laboratory Name is the name of the laboratory in which the sample was analyzed.
Analysis Methodology*	The Analysis Methodology is the analysis method used to generate the reported result. This must match the allowable entries verbatim.
Nuclide Type*	The Nuclide Type is the name of the analyte reported in this row.
Result*	The Result is the numerical or qualifying analytical result.
Result Unit*	The Result Unit is the unit of the numerical result.
Uncertainty/Error	The Uncertainty/Error is the absolute total propagated uncertainty for the analytical result in the units of the result.
Coverage Factor	The Coverage Factor is the statistical coverage factor for the result uncertainty (e.g., 1-sigma or 2-sigma).
MDA/MDC	The MDA/MDC is the minimum detectable activity (or concentration) for the measurement reported.
Measured Critical Level	The Measured Critical Level is the critical level for the measurement reported.
Quantity as Analyzed	The Quantity as Analyzed is the quantity used in the analysis of the sample. If the sample was analyzed whole, this is the whole mass of the sample. If subsampling was done, this is the mass of the subsample.
Quantity Unit	The Quantity Unit is the unit for the reported sample quantity measurement.
Wet or Dry?	The Wet or Dry? field indicates if the sample was dried prior to analysis. If the sample was measured without drying, Wet is used. If the sample was dried prior to counting, Dry is used.
Comment	Comment is an open-text field used to communicate any information to data reviewers about this result. Please include any laboratory-defined data qualifiers, batch IDs, or notes on the validity of the result or issues in the QA batch here.
Upload Type	The Upload Type is used by the staff uploading this result to RadResponder. Valid entries are “No Change,” “New,” “Update,” and “Append.” When updating a record, a combination of sample number, nuclide type, and analysis method are used to link results.

UTC = Coordinated Universal Time