Rigshospitalet

PET & Cyklotronenheden

Technical documentation and risk assessment for Tracershop

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Resume

This document describes the current Tracershop ecosystem, a bookkeeping system for the production of radioactive tracers for clinical procedures produced at Rigshospitalet. The system was designed in 2004 and in the field of Computer Science such a system is considered ancient. This document presents a replacement system with the aims to improve the user experience, functionality, and improve IT-security, namely a react-django new web server and makes a risk assessment of the current and the new system.

Tracershop - Current system

The original Tracershop was originally produced in 2004. Various contributions to the ecosystem have been made over the years, however development the system stopped around 2012. The main functionality of Tracershop is fulfilling the documentations requirements in Rigshospitalets production of radioactive tracers specified by GMP. Rigshospitalet delivers radioactive tracers to many hospitals and scientific institutions, that would not be able to perform various PET and SPECT scans without the tracer. Therefore Tracershop should be considered a important piece of software.
The system is centered around a MySQL 5.1 database running on a openSUSE 11.2 distribution, which contains all the records and logs about the production of tracers. This database is back up on an external machine every day at midnight. The user interface is a Zope 2-2.13 web interface allowing the users interface with the main database. It is normal that software packages deprecated after a period of support, and keeping a software product up to date is part of the maintenance of a software products life cycle, however that have not been possible due to insufficient resources.
An overview of the system can be seen in figure 1. The dispenser ensures the amount of product in vials and

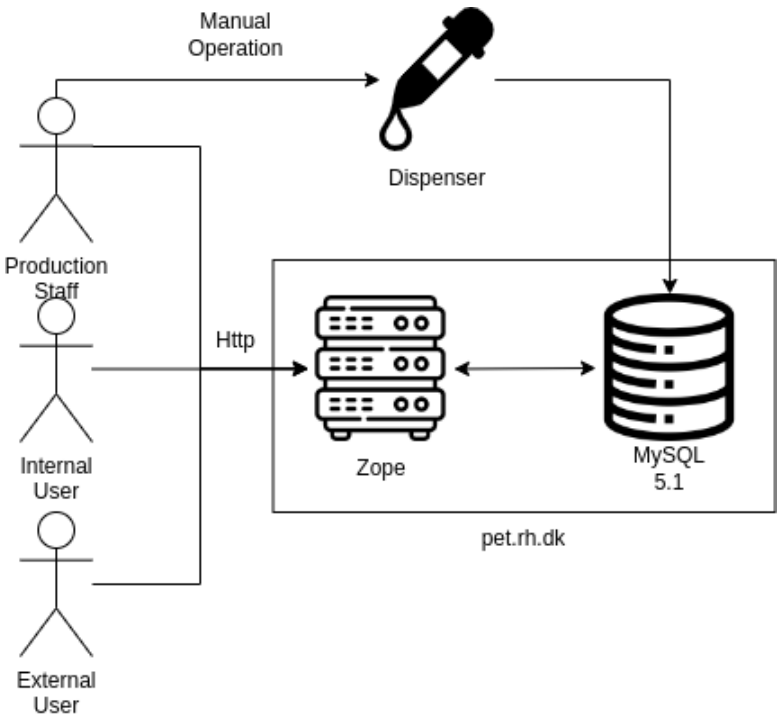

Figure 1: Tracershop system overview

the digital record of the product are equal. The dispenser writes these records to it own database, which does not support multiple concurrent connections, making it impossible to retrieve them the conventional way. A script circumvents this obstacle by opening the database as a file, and by using a byte offset retrieves the data of the dispensed vial. This solution is highly fragile, and an update to the database could change the file format of the database. This would render the script inoperable as the byte offset would no longer be correct.
Should the offset be incorrect the script would read garbage, so it could not construct a valid entry and thus would mostly likely fail. In that event the production staff would have to manually read the data from the dispenser and then write the data into Tracershops database, which introduces another human error.
It's therefore recommended to replace the dispenser, with one fulfils the requirements of either:

- Writes dispensed tracer data to a database that allows multiple connections.

- Writes dispensed tracer data to a file.

Currently it's the The Department of clinical physiology nuclear medicine which hosts the server. Which is not desired because hosting server is a core task CIMT and not the clinical departments.

Abstractions

Tracershop handles two different types of orders. Activity based orders and Injection based orders.
An **activity order** is defined as an order, where the user orders an amount of MBq radioactive tracer at a predetermined time slot known as a "deliver time". It's the user responsibility to account for radioactive decay between injection time and delivery time.
An **injection order** is an order with a number of injections with a predefined amount of activity, and it's Tracershops responsibility to account for any decay between production time and injection time. Users er limited per user basis which injection tracers they can order.

Requirements

- A user can order radioactive tracer from the internet while not connected to the Capital Region intranet. A user can be limited in their selection of tracers and limited time window where such tracers are available for ordering.
- A user can review any order they have made, and view batch number of tracer that they have ordered. They cannot view or alter order, which doesn't belong to them. They cannot alter delivered orders.
- A released order has a batch number and a record of who released it.
- Non authenticated users cannot alter or view information in tracershop.

Database layout

The Tables in the Tracershop main database, note the tables casing does not conform to the snake casing that standard for SQL databases:

1. Log - Likely Zope related. No longer in use as the last entry was in 2010-03-18.
2. MiscData - Likely Zope related. Likely a temporary value container.
3. Roles - Zope related, defines different user roles in the Tracershop program.
4. Sessions - Likely Zope related, defines active user sessions.
5. Tokens - Likely Zope related, Likely defines the length of active sessions.
6. TracerCustomer - Defines which user have access to order which injection Tracer.
7. Tracers - Catalog of tracer available in tracershop.
8. UserRoles - Relates user to a Role from the Role table.
9. Users - All users able to be authenticated in tracershop
10. VAL - Record of a vial with tracer, produced by the dispenser.
11. VAL2 - Not in use.
12. blockDeliverDate - Extraordinary dates where tracershop is closed, such a holydays.
13. deliverTimes - Weekly points in time specifying when a customer can place an activity order.
14. isotopes - Catalog of radioactive isotope used in the tracers.
15. orders - List of activity orders.
16. productionTimes - Weekly points in time, where a production should happen. Entries are also referred as a run.
17. productions - Production of tracers.
18. storage - Old mails, assumed not in use.

19. t_orders - List of injection orders.

The database are not utilizing the foreign key restriction, meaning that the relations are ensured at application level and not the database level. It's recommend to utilize the these functionality to ensure that the database stays in a valid state. For instance if a tracer entry is dropped or updated, it may not be possible to determine the tracer of any historic order, that might have used this tracer.
Despite Activity orders having a tracer field, this is ignored by the Zope application and assumed to be FDG.

New web server

Tracershop is a system of individual components, so a simple switch of system is not advised, as any of new components would likely contain early adopter errors. While these errors likely are easy to resolve, they would still take the system down, which is unacceptable. The best plan of action would be replace each individual component one at a time. If possible the old component should be running as a backup in the event that a new component has an error and is unavailable.
The largest but easiest to replace component is the web server, as it can connect to the old MySQL database and therefore can co-exists with the old system, as long as the old and the new web server follows the same assumptions. Once the new tracershop is considered stable, the Zope web service can be discarded.
This report suggest a django web server with a react front end. The project is open source found at:
https://github.com/demiguard/Tracershop
The new system uses common software packages for web servers:

- React - Frontend Javascript library developed by facebook. https://reactjs.org
- Django - Backend Python web server library https://djangoproject.com
- Channels - Django extension for using websockets. https://channels.readthedocs.io./en/stable

These packages are well supported and all in active development, so their developers will continue to provide security updates.
The new Tracershop utilize websockets instead of http communication, because websockets allows the server to push updates to the users unprompted, because the protocol uses a persistance connection, while http does not use a persistent connection. An overview of the communication can be found in figure This means that

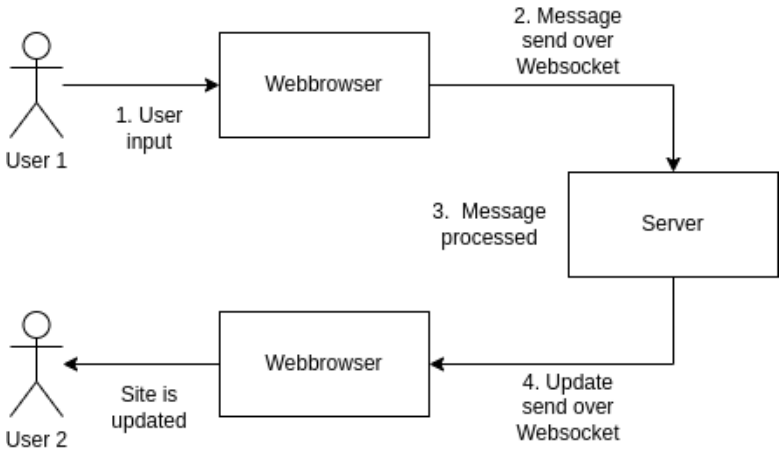

Figure 2: Overview of the message handling.

user always view up to date data, while in old system users might operate on out of date data, if another user have altered that data. The new system should be hosted hosted on CIMT servers, which would be in line with Rigshospitalet policies regarding software.

To ensure that the new tracershop handles message correctly behavior and follows requirements of GMP. The message is p in a three step plan seen below:

1. Validate the message - ensure that the message is correctly formatted and therefore would not cause an error if processed by the web server.
2. Authenticate the message - Now the server can assume, the message is of a valid structure and determine it type. Then it can check if the authenticated user is allowed to complete such a message.

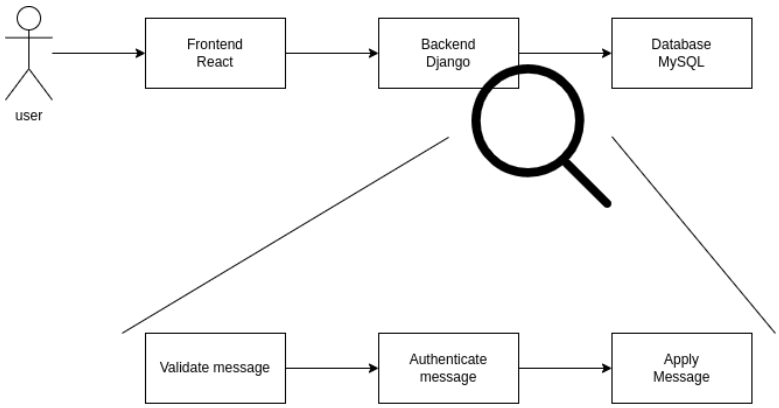

Figure 3: Message handling by the backend

3. Apply the message - Now the message is both valid and authorized, so the server will handle the message.

Since the frontend doesn't have any contact with the database, it is sufficient to ensure that the backend handles the users messages correctly. This is done by a series of unit tests and end to end tests, which have a 92% code coverage. Which means that there's a program, which creates a test environment and run a number of tests where 92% of all statement in the program is executed at least once. Having above 90% code coverage is considered good coverage as not all code is easily testable, nor does a code coverage of 100% ensure that the program have no errors. The testing proves the web server with high confidence handles messages correctly.

The django application has its own database to keep track of user session, which have been extended to to include general web site configuration. This means that the django application database doesn't contain any records of orders or customers. This allows easy creation of test environments, since the record database is a field in the django database, it can be easily exchanged to a connection to a database with a test environment. There's a also a Regis database required by channels to exchange messages correctly. For performance reasons these databases should be running on the same machine.

Test highlight

This section highlights a number of test cases which ensures that

Risk assessment

A risk assessment is a collections of risks, each risk consists of a description, a likelihood of how likely an incident is to occur and a damage estimate of an incident and final a plan of action if an incident happen.
This risk assessment doesn't include malicious usage of tracershop, production related risks. Additionally it assumes correct data from the dispenser as both the program transferring and producing data have modified by the new Tracershop, and therefore derives its validity from previous documentation Se document number.: CVP-PROD-TS-001-14.01 in the D4 document management system, for the latest validation of the dispenser.

- Loss of a server.

Description - A hosting server might become unavailable for a number a reasons: A foreign threat might encrypt the entire server, or a critical files might become corrupted due to aging hard drive. This is not an exhaustive list of reasons for server loss, but it's beneficial to have plan of action in the event of an incident.

Likelihood - Low to medium - Currently the service runs on old hardware, insecure protocols and outdated software. Which raises the likelihood of an incident occurring. Switching to CIMT hosted service with the new web server will eliminate these problems.

Damages - Medium to critical - Currently if a server becomes unavailable the source code to the original tracershop is lost. This means that restoration of the old system is impossible. Additionally any records made since the last backup would be lost. Due to the daily backup, this would be up to 30 orders.
In the event, that both the backup PC and the server would become unavailable simultaneously all records would be lost. Due to the fragility of the dispenser script, automated import of vial data could be unavailable for a long period of time.

Plan - In the event of server loss, if the loss was coursed by faulty hardware, repairing the server hardware might be possible and could restore the system to a pre-incident state, within 1-5 working days. If that's not possible to repair a new server is required. Assuming that the system is not deployed on CIMTs services and a spare server is not available, procuring a new server would take between 4-12 weeks with a 1 week installation period afterwards. Due to limited experience with replacement servers from CIMT it's unknown how quickly they could procure a new server, however the installation period would remain the same. If the server is virtualized and backed up, and the back ups are not lost, then the downtime would be around 1 day.
In the cases where the original source code is lost, the new solution would be forced to be used. Note that the new solution doesn't suffer the same vulnerability due to be hosted online. In the case where github becomes unavailable, a replacement service would not be difficult to find as github is build around Git.

- Database is brought into an invalid state.

Description - Due to the fact that it's the application responsibility to ensure correctness of the database. If the record database is in an invalid state, undefined behavior might occur or the data might be invalid. Consider an example where a tracer is deleted. All orders with that tracer can no longer be determined to be of that tracer.

Likelihood - Low - The web services doesn't allow, the user to perform arbitrary SQL queries. Only predefined queries that take the database from one valid state to another valid state. However it's difficult to ensure all possible user inputs. Hence it's possible that a user query might bring the database into an invalid state. Another way an incident could happen is if a system administrator creates a query that brings the database is into an invalid state.

Damages - Low - The new tracershop can handle invalid database entries to an extend, meaning tracershop still works for unrelated entires and therefore not take the service down. The system will instead display, that certain information is undefined or not display the incorrect data at all. If the invalid state persist unnoticed for more 1 day the backup will be over written and the damage made permanent. However in such a case, it's unlikely to critical data, that have been corrupted.

Plan of action - A system administrator would go into the database and revert the database. All queries made through tracershop to the record database is logged, which can greatly help system administrator to undo the damage. In worst case scenario is to restore to a backup of the record database.

- Incorrect user input

Description - Tracershop have a number of fields, where the user must write some data in. Because it's humans that write this data, the system is subject to human error. It's incredible difficult to prevent this as there's nothing inherently wrong with incorrect data user input. This also includes whenever a user forgets to update a piece of data.

Likelihood - Very high. Humans use this program, no further elaboration required.

Damages - None to Low - Very often human error will be spotted even ever a fresh set of eyes is looking at the incorrect data. Whenever this happen the plan of action can be applied and most likely reverse any damage done. Incorrect data is also likely to cause other data become incorrect, however it's possible.

Plan - The new tracershop allows user to edit non committed information their, and require users to sign in whenever they commit something to tracershop, while the information about to be committed is being displayed. Should the incorrect data be committed to the database, the personnel who finds the incorrect data should contact the system administrators and await their instructions. For instance if an order is committed with insufficient vials, the system administrator will request the personnel to create an additional order with the remaining vials.

- The dispenser script stops working

Description - As stated above, the program that ties the dispenser and database is highly fragile and could break, if the database is updated or if the hardcoded ip addresses changes.

Likelihood - Low to medium - A user might accidental update the dispenser, or original server might be moved. However despite all of the alarm bells of fragility ringing, the system have been operating for 12 years.

Damages - Low - The service would be very difficult to repair, due to the author of the program no longer working at Rigshospitalet, and is a forking perl script. However the loss of the service would not incorrect or invalid data by itself. Only an additional source of error and additional human labor is required.

Plan - Users would be forced to manually input data, that normally would have been transferred automatically and correctly.

- Email server is unavailable

Description - The email service is external, thus may for any reason be unavailable for an undefined amount of time.

Likelihood - Unknown - The author have so limited experience with the available of the mail server, that a valid likelihood estimate is difficult to make.

Damages - None to low - Customers are required to wait for confirmation that the tracer passed quality assurance mandated by GMP, so if the email server is down, the customer can not be notified through email.

Plan - Due to websockets, updates to orders can be seen on tracershop in real time. Additionally users can download the email from tracershop from the associated order if needed or internal bookkeeping without any emails involved.

Conclusion

The old tracershop fulfils the requirement set forwards by GMP, but is running on modules that have reached end of life.

A new system is proposed, that fulfils GMP, no longer uses, and improves various aspects of the tracershop system. An extensive test sweep ensure that the django web server handles messages correctly.

Glossary

CIMT Center for IT and Medico technologies. Responsible department for IT in the Capital Region of Denmark. 2–5

FDG [^{18}F]Fluorodeoxyglucose, a common radioactive tracer used for PET images. 3

Git Git is a free and open source distributed version control system designed to handle everything from small to very large projects with speed and efficiency. Found at https://git-scm.com. 5

GMP Good manufacturing practice, created by the EU and Danish medicines agency.. 1, 3, 6

incorrect data Data that doesn't reflect reality. Examples include a misspelled batch number or an activity entry which does not match actual activity in the vial.. 5

invalid data Nonsensical data that could never be valid. Examples include a reference to an nonexistent object or Negative halflife or activity.. 5