Common Information Spaces in Novo Nordisk

Distributed Multimedia Technologies and Applications
Task 1.2
Communication and collaboration in network organisations
Common information Spaces

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Introduction

This document contains the descriptions of the initial study of the use of common information spaces in Novo Nordisk.

It has two functions. Firstly it allows us to be certain that we do not inadvertently use information that should not be brought outside Novo. Secondly it serves to pass on information from phase one of the project to phase two, where a new researcher joins the group and a researcher from the original group reduces the involvement.

At an earlier stage in the project parts of the document were used to catch misunderstandings, by going through the descriptions with the persons who were observed or interviewed.

Here the names of departments are used to make it more useful to Novo - when the material is used outside Novo the names will be changed. To avoid accidental use of real names anonymous names were used while writing this documents. These have been replaced with the real names in this document except for Docman and QBIQ, which are referred to as respectively the old and the new digital storage, abbreviated DS.

First the organization is briefly described, then the three systems: RMC, Docman and QBIQ and then the use of the systems in Immuonochemistry and Legal Discovery.
1 Common Information Spaces in Novo Nordisk

Here the overall setting of the investigation is presented. The company, its environment and the two major shared information systems are described.

1.1 Introduction to the company
Novo Nordisk is a large medical company that develops and produces various types of medical drugs. Recently the company has been split into four separate companies corresponding to four focus areas. Still the work is characterized by being accomplished in a huge organization with cooperation among many actors and groups. The process from idea to having a product on the market takes several years and among others involves such areas as development, clinical tests, production design, production, continuous testing, packing and distribution, government approval of the product, marketing, legal support, documentation and strategic management.

The cost intensive nature of the pharmaceutical industry brings with it a demand for large-scale production. The company thus markets the products globally. Other reasons for international presence and cooperation across geographical and national distances exist. For instance cooperation with foreign research institutes and doctors is motivated by the populace of these countries being more obliging towards participating in medical tests. It may be interesting to note that this is not a result of difference in payment structures between the countries but rather of ethical issues.

Of central importance to the structure of the production system is the legal structures in the health area. Because of the extent (in number of affected persons and severity) of potential problems of a drug with unforeseen side effects, the area is highly regulated. Errors or inexpedient happenings can well lead to a company having to shut down. This leads to a structure where documentation of the processes and tests of the products are just as important as the product itself. On regular basis inspections of facilities and documentation are made by official institutions and representatives of collaborating partners.

1.2 The major systems
Two systems meet the eye when approaching the information systems in Novo Nordisk. They are spread through most of the organization, are used often and in relation to areas that are essential to the organization, contain very large amounts of
data and have separate support units. Furthermore they are introduced and sanctioned by the top-level management. In the following two sections the systems are described.

It should be noted that in addition to these systems several other systems exist. A few examples of other shared information structures are: a web-based intranet, NT workstations and networks for file-sharing, a SAP economy system, small e-mail-based workflow systems, smaller local databases, shared logbooks and locally maintained archives of scientific articles, books, reports and contracts.

Using the two major systems and their relation to the other systems as the basis of the investigation is simply a question of choosing an approach that fits the objective of the investigation. This approach eases the process of identifying areas to investigate further and directs attention to the overall organizational use of shared information structures. The approach however to some degree is in danger of forcing the perspective of the designers and maintainers of these systems on to the observations. As long as the analysts pay attention to mismatches between the perspective and systems used in different part of the organization this is not a problem, rather it allows an interesting investigation of the nature of these mismatches. In addition the next round of empirical investigations can use these initial results as basis, but use another approach to the area if this is deemed interesting or necessary.

1.2.1 Records Management Center

The Records Management Center, is a large central physical storage keeping many types of documents and data. The documentation is supplied and used by a range of departments to support a heterogeneous set of activities. For instance the documentation in the archive is used in relation to legal permissions to produce and market pharmaceutical products and is needed for patent and product registrations.

Function

Because of legislation and market structures it is necessary to keep documentation of many aspects of the activities in Novo Nordisk, in addition it is useful in relation to inner processes. The potentially needed documentation for instance includes validation of processes and systems; results from research and test and various data related to specific products. This documentation for instance is used in relation to
approvals of products and inspections by public authorities and other supervising institutions; by the legal departments in relation to cases concerning patent rights or product liability. Documentation producing departments also use this type of documentation, from other departments as well as from own production.

The documentation is stored in a central archive that has three main functions:

1. Collecting documentation
   The purpose with the RMC is to collect all the relevant documentation in one place to allow easy access to needed documentation at all times and that it can be found without having to depend on persons or local archives.

2. Storing documentation in a secure way
   The documentation is stored centrally in a secure facility protecting the documents from decay and physical damage as well as from access by unauthorized parties. Documentation may be needed more than seventy years from the production date.

3. Providing access to documentation
   The employees maintaining the RMC mediate access to the documentation and keep a register with index information to be able to find documentation that meets certain description.

The figure describes part of the function of the material storage unit, inputs, outputs, and suppliers and users of information.

**History**

The system has had this form in only seven years. Before that the information was kept locally. The present form was chosen and imposed by top level management because the old structure led to documents being lost - either thrown away or not possible to find, for instance because of people leaving the company. The current system is state of the art in the area and Novo Nordisk was rather late to change to a
central structure - some medical companies have had this type of structure for thirty or forty years.

The present computer system is an emergency solution, going back three years. The problem was that the digital storage is not able to meet the demands related to this part of the documentation, since the system is not “retrospective”. That is, it is not able to document how things have evolved but can only show the present status. Novo Nordisk had to find a suitable method quickly. In relation to this validated systems and the existing competencies were central. For instance Novo Nordisks IT department has a list of supported systems, which could be used to avoid additional training time.

**Material Storage Unit**

An organizational unit, Material Storage Unit, RMC-unit, is dedicated to the operation and development of RMC. All parts of the work related to the RMC are done in accordance with a set of procedure regulations. For instance requested/allowed types of materials, delivery deadlines, packing, access control, marking, lending of material is described.

The RMC-unit has thirteen employees compared to three six years ago and is split into several smaller functional areas. People work together across these areas and all of the employees take part in development as well as normal operation. There is a large difference in age, a small majority of women, large variety in work experience and educational training. However many of the employees are librarians and two hold a Ph.D.

I addition to maintaining the archive the unit takes part in interdisciplinary development-projects and offer internal courses concerning use of local archives (security), rules for using the RMC and packing and marking documentation that are to be added to the archives. That is customers of the RMC are not necessarily the same as customers of the RMC-unit. Here the term “users of the RMC” is used about users of the documentation in the archives. This use however is assisted by the RMC-unit, which also grants access. The RMC-unit also visits units to learn. For instance
about changes in the situation, e.g. new products, to be able to meet the storage demands.

**Stored material**

Documentation may be relevant for more than seventy years. Some types of documentation must be kept until thirty years after the product is not sold anymore. The documentation in the RMC goes back to about 1940 with an overweight of material from the 90s. The database contains more than one hundred thousand entries (often with several documents related to each) but much material has not been indexed and added. Continuously new material is added, for instance only thirty percent of the material added in May 2000 was from that year and material from the 70s were among the added items.

It is not possible to give an exhaustive list of the types of documentation. They are too many and too different. As mentioned the documentation comes from all parts of the organization (among others research, tests and production) and varies in content (raw data and reports, validation and analytical data from production) and in form (paper based documents, digital documents or samples from tests or production). This is not a problem but an important realization that it is at times necessary to make structures that can handle objects not well defined at run or design time. It also as it is discussed now stresses the usability of high level categories.

The archived data is divided into four categories. This split is mainly caused by technological limitations at the time of the implementation of the system. The available database system simply did not support databases of the size. The categories are:

<table>
<thead>
<tr>
<th></th>
<th>Pre-clinic</th>
<th>Clinic</th>
<th>Manufacturing = Department related material</th>
<th>Support data = Department related material</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before clinical tests</td>
<td>During clinical tests</td>
<td>Related to product (e.g. labels)</td>
<td>Data not related to specific studies of projects</td>
<td>Validation from production</td>
<td></td>
</tr>
</tbody>
</table>

The classes have very different contents and most relate to one specific set of standardization e.g. GLP (laboratory), GCP (clinical), GMP (manufacturing) and GSP (scientific).

**Archives**

The archives consist of several storerooms and associated databases. The archive contains boxes packed at the supplying units, which are sent in with a description and
an indexation. In RMC the indexation is transferred to the systems and the boxes are stored.

**Structure**

The archives consist of two main types of structures: the storage and the database to support it. More than one type of storage exists and two databases of which one is split into three subcategories as described in the section “Stored material” are used.

The way that the heterogeneous set of documentation is handled is discussed in this section. A point of departure is this simplistic sketch of the system. Support data goes into “database I” where a pointer to a central digital storage is made. The documentation itself goes into “Storage”, associated description and other index data is added to “Database II” and potential samples goes to “Wet storage”. The record in “Database II” includes information of the location of boxes and wet samples in the storage rooms.

A sketch of the storage. The types of documentation are discussed in later in this section. Arrows denote that data are placed in an archive or that a reference from an index to an archive exists.

Documentation is described by the persons producing it. This description goes into the index in the database with the physical location of the material in the archives (shelf number, box/drawer and possibly row) or with a reference number to the digital storage.
No keywords or categorization of the material are used. It is estimated to laborious to introduce it and the work tasks can be done efficiently without it. It is thus central that the description provided by the producers is sufficient for the various uses.

The figure below shows the type and extent of information of the documentation found in the index in RMC.

The list of types of material is a table of content of audiovisual material and of digitally stored information (e.g. CDs or floppy discs). Since Novo Nordisk's partners use other numbering schemes than DM these numbers are used in the system as well.
Links to DS and to wet samples. The clinical documents for instance contain doctor reports on each patient, comments by national ethical comities and a main report. A trial master file is the collection of all these and will often take up between one hundred and three hundred binders.

Clinical and pre-clinical data is related to project numbers and study numbers (trial numbers). Another index type for department data (department numbers) and validation data (related to batch numbers and various running indexes). CMC is related to a product name. Some of these numbers are somewhat standardized and universal, but most are locally determined and a total overview is not possible. (An attempt to construct a list of projects and numbers took up forty printed pages).

It is seen as very problematic to work with the numbers. For instance the project numbers are re-used and previous mergers have led to different projects having the same numbers, and department numbers and initials of employees change. As persons with knowledge of the documents leave Novo Nordisk (secretaries are key persons here) it is becoming more difficult to handle the situation.

Universal bar coding is though of as a way to meet some of these problems. This it is not implemented as yet. The prize of a such system is of major importance in this.

The schemes that are used are made by RMC-unit in collaboration with the departments and the various quality units. The clinical and pre-clinical areas were easy, whereas manufacturing related was more difficult. It took a couple of month to make the schemes through a process of suggestions from RMC-unit, comments and discussions in the organization. The scheme is not changed - this would involve huge problems for the archived material and the sorts of documents are not expected to change. The things that have digital versions are easily distributed for instance to foreign sites.

*Physical setup*

Physically the archives are large storerooms with numbered shelf systems secured against fire and with access control. Documents are archived in the order they are received. Most of the data is kept in identical standardized cardboard boxes (various
sizes exist) free from acid and without plastic. They are potentially sub-ordered in standardized envelopes.

Boxes and envelopes are marked with a label with a description of the content. This label corresponds to a sheet of paper with a description of the material kept in the box. The information labels are standardized but several versions exist corresponding to the various types of documentation. They are marked with content (e.g. project number, study number; batch number and date or date intervals or a description), name of the archive, number of the department delivering the material and placement (filled in by RMC-unit). Each box and envelope corresponds to records in the database where the description is found with the physical location of the box/envelope in the storage.

Two types of material are handled differently than standard boxes: some samples are kept in the “wet archive” and data that refer to patients are kept in a sealed container.

The wet archive contains “remains from animal experiments”. These have a shape and nature that demands a different storage form, for instance constant temperature on sixteen degrees and another shelf format. The special format means that they can have a row location assigned as well. Every sample corresponds to a pre-clinic storage in the archive. The samples are in the shape of tissue kept in preserving liquid or blocks of wax and slides (that are similar to the glass sheets used in a microscope). Exotic examples on stored materials are mice fetus and guinea pig heads.

The data that refer to individuals can not be kept in a central register of the form described above according to legislation. A separate storage with highly restricted access and special control measures is required. This type of data is usually information and measuring data from patients participating in test of products.

**Using the archives**

Several groups are in contact with the archive. First of all of course the unit that maintains the archive. The management use data from the archive to inform management decisions. Several units with functions in relation to research, test and production deliver material to the archive and make use of material stored there either
by them selves or by other units. Units concerned with the approval and legal issues use the stored material. The users can thus be classified as suppliers and users of the information in the archive but many suppliers are also users. Here the use is split up in adding material and getting material.

In 1999 almost six thousand boxes were delivered, many of these with several documents in them. Almost ten thousand records were added to the database containing clinical, pre-clinical and manufacturing related documentation and about three hundred and fifty validation documents were added to the other database. About twenty thousand copies of archived material were made to allow access to the archives. In addition the archive was accesses through three hundred visits by internal personal and two hundred visits by external personnel.

The use and delivery situation is characterized by pronounced and unpredictable inconsistency. This is mainly a result of delivery and demand being influenced by currently important projects and cases. RMC-unit tries to keep informed by the other departments of when to expect busyness but since the reasons are often external and unpredictable this is only possible to a limited extent.

A central idea is that it must be worth it for the users to use the system. This of course is mainly a problem in relation to people who mainly produce information. Structures and functionality that make it easier to pack information and allow valuable use of the RMC is thus continuously developed in RMC-unit.

Adding material
The producers of documentation pack the boxes/envelopes according to regulation of content as well as method of packing. The material is packed in boxes at the place of the production of the material by the people producing it. The documentation is packed in envelopes marked with “study no.”, “trial no.” or “other unambiguous description” or ordered with “snapbinders” (paperclip like devices that do no break down the paper) after which they are packed in boxes. The format of the verbal description added is to some degree specified by procedures of RMC and RMC-unit checks whether it corresponds to this when checking the material into the system.
The producers also fill in a form corresponding to the nature of material with a description of the material and a label that marks the box/envelope with part of this description. This label contains: content (e.g. project number, study number; batch number and date or date intervals or a description), name of the archive, number of the department delivering the material. The material is then handed over to the RMC where it is controlled if it meets the demands for archived material. The description is entered into the database. Here the box/envelope is assigned a place in the shelf system, where it is placed.

The description is made on a (in Novo Nordisk) standardized form identical for all users of the storage but not standard for the industry exists. Four indexation forms are used: Pre-clinic, Clinic, Manufacturing related and Department related. The figure below shows which information they contain.

<table>
<thead>
<tr>
<th>Common fields</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>department name</td>
<td>department no.</td>
</tr>
<tr>
<td>name of possible substitute</td>
<td>signature</td>
</tr>
<tr>
<td>Pre-clinic</td>
<td></td>
</tr>
<tr>
<td>study number</td>
<td>study name</td>
</tr>
<tr>
<td>report: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>appendix: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>study plan: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>appendix: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>unforeseen events: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>raw data: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>other documentation: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>Clinic</td>
<td></td>
</tr>
<tr>
<td>trial no.</td>
<td>trial name</td>
</tr>
<tr>
<td>#</td>
<td>DS ID</td>
</tr>
<tr>
<td>Manufacturing related</td>
<td></td>
</tr>
<tr>
<td>study number</td>
<td>study name</td>
</tr>
<tr>
<td>product no.: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>production procedure: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>logbooks: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>validation documentation: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>other documentation: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>several other types 17 in all</td>
<td>description</td>
</tr>
<tr>
<td>Department related</td>
<td></td>
</tr>
<tr>
<td>study number</td>
<td>study name</td>
</tr>
<tr>
<td>procedure: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>logbooks: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>raw data no related to study: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>equipment documentation: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>other documentation: description</td>
<td>DS ID</td>
</tr>
<tr>
<td>several other types 10 in all</td>
<td>description</td>
</tr>
</tbody>
</table>

A standardized form is filled in and delivered with the documentation. Four types exist: pre-clinical, clinical, manufacturing related and department related. They have a few fields in common.
Validation documentation is specifications of requirements that equipment, processes, computer systems and the likes has to meet and documentation that the requirements are actually met. Validation documentation from the production is added without using a form. Printed versions are kept also of digital documents.

The RMC also contain documentation from partners, who then use a special field for their unit number within this organization.

Floppy discs are received as documentation, they are stored in envelopes and boxes as the paper documents. The disc itself must be marked in a way that “unambiguously identifies the disc.” e.g. study no., project no. Media other than paper are registered specially to allow later backup of the content.

The RMC-unit goes through received material verifying that the documentation is as is should be. The investigation encompasses:

- checking if the description matches the contents
- if the material has been prepared properly
- if the labels on the material matches the description
- special check of clinical material
- control of the sealing on the data referring to individuals

Problems are resolved either by contacting the responsible person in the department delivering the material or simply by sending the material back for re-packing.

A receipt is produced and sent back to the department.

<table>
<thead>
<tr>
<th>archive no.</th>
<th>department name</th>
<th>department no.</th>
<th>project no.</th>
<th>study, trial or batch no.</th>
<th>title</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>delivered by</td>
<td>date</td>
<td>received by</td>
<td>date</td>
<td>signature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The figure shows the information returned to the producers as a receipt.

*Getting material*

Searches are made on the indexation provided by the suppliers as it described above.
Some users use it almost every day, other once every other month. It mainly depends on the projects and work areas that are currently active.

The users of the archived information either get data automatically (monthly status report) or contact the RMC-unit about specific documentation. This enquiry can be specifically directed to a piece of material know to exist in a certain box or it can be of more general nature.

Access is allowed only with permission and forms have to be filled in when requesting access to the archives. Access is restricted so that only persons holding specific positions (responsible persons in departments, management, substitutes for these) are admitted to the archives. Material can either be copied in the RMC or taken out from the storage. Forms are filled in when material is accessed or taken out.

Every month a report is made with statistics from the use. Incoming material and use are summarized and analyzed to be able to meet demands. As these reports are sent “up” in the organization it is a conscious choice to draw attention to the heterogeneous uses of the storage to point to the benefits of improving and expanding the offered services.

Copied documentation is stamped “EXACT COPY”, marked with the placement of the original, dated and signed. An exception is validation documentation this is only stamped when it is used by parties who are external to Novo Nordisk.

Access to the data is classified in relation to the use of the data. The categories are meaningful in the RMC and are determined by asking the users before they are admitted to the data. An example of the use in one month follows:

<table>
<thead>
<tr>
<th>Type of use</th>
<th>percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge management</td>
<td>21</td>
</tr>
<tr>
<td>Misc.</td>
<td>11</td>
</tr>
<tr>
<td>Deviation</td>
<td>11</td>
</tr>
<tr>
<td>Authorities</td>
<td>11</td>
</tr>
<tr>
<td>Regulation application</td>
<td>5</td>
</tr>
<tr>
<td>Advisory (training)</td>
<td>41</td>
</tr>
</tbody>
</table>

The distribution varied heavily between month and other categories are found in other months, for instance legal and quality.
An especially interesting type of use is the use as “knowledge bank”. This function is spreading. The RMC have “knowledge bank” requests between five and fifteen times a month. The type of enquiry is thus rather rare but it is growing more widespread. Handling an enquiry of this type can take from an hour to one and a half day. This type is interesting because the person requesting data here does not ask for specific data that can be found through an unambiguous reference (e.g. box or study number). Instead he has a subject and wants to find information related to this in the archive. This demands another type of functionality that currently often requires knowledge of the RMC possessed by RMC-unit personnel and not represented in the systems.

Examples on this type of use of the system are:

- validation of refrigerators across projects to make standard in the area
- a skillful expert with unique methods that people later wished to examine and learn from
- the construction of a “museum” (promotion, support of organizational culture) and thus the need for finding particularly interesting items with a historical importance
- and in general re-use of experiences from parallel studies where exact project number is unknown

Further observations

The structure is obviously not inexpensive but the expense is deemed necessary in consideration of the potential consequences of not being able to meet the documentation demands - in fact it is a requirement from FDA (American authorities) that the system is structured as it is.

Currently the unit works with digital signatures and various ways to store information digitally to move towards the benefits of digital storage (e.g. less cost, less occupied space, easier/faster access, reduced need for copying, new ways of securing data).

1.2.2 Digital document storage

The second system contains information shared in electronic, digital form stored in computer systems. The system is based on a central database that contains documents and meta-data. It contains many types of documents (e.g. operating procedures,
documents related to clinical studies and minutes) with different sets of meta-data connected to various types. The system is used for several purposes and is continuously being developed.

**History and functionality of the system**

An increase in the use of digital documents by the FDA in USA was the main reason for introducing the system in 93. The public authorities started encouraging use of digital information, for instance burned on CDs. No standardized format or interchange formats where used. The information was simply delivered in digital form with a system that could read the information, for instance a computer with corresponding software could be delivered with the digital information. This development in the public sphere has however not come as far as expected, so communication with public authorities is still paper based.

*The original system*

The original system was planned to have many application areas, some of these not planned in advance by the designers. The use of the system was to some extent expected to come by itself as opposed to planned beforehand and forced upon the potential users. The system is used through a piece of internally developed software and it is necessary to be registered to use the system. The system had a slow start, but after some time an increase in management focus on the system led to an increase in the use of the system.

TOC is used in the old system with a couple of other presentation methods, mainly search on meta-data and TOC. It is used to create an application tree structure.

*The new system*

This increase was also related to the development of a supplementing system that brought additional functionality into a delimited area of the documents. The new system can be seen as a superstructure to the old one. All documents are still stored physically in the old system, which also administers access-rights, the new system only contain pointers to the database.

The new system is web based and allows access to the subset of documents by all Novo Nordisk employees. All documents can be found with title, the actual document
is protected in a few cases, here it is required to be registered as user on the original system and to have access rights to the documents to be able to access them. A more easily approached interface in general is expected to have promoted use of the system for instance new presentation modes were added. This allowed easier navigation in the documents and is considered one of the reasons that more people started using the system.

The new structure was built to support the work with a specific type of documents. It handles operational documents (for instance Standard Operating Procedures, abbreviated SOPs, and Supplier Agreements). This part of the system thus allows the employees access to all relevant procedures in their valid form.

The documents are kept in a local storage with a large shelf system with a file for each number. Earlier this storage was physically divided into current and obsolete versions. Today the files contain all versions of the documents. Only documents in the new system are kept like this, but both present and obsolete documents are kept there.

**Digital Storage Unit**

The system is maintained by two internal units. One unit deals with the technical aspects e.g. maintaining the hardware, development and adding users. The other unit deals with the content of the system. They see themselves in some aspects as “super users”. This is the unit of concern here and is referred to as the digital storage unit, Documentation Center. Design and implementation was done in collaboration with an external IT-consultant firm. The system had the ideal of “providing the right documents at the right people at the right time”.

Actually five Documentation Centers exist. One unit deals with approximately ninety percent of the material in the system. In addition two units are at another location in Denmark and a unit is found in USA and in France. These are by an employee described as “a another world, with completely different needs”. The central unit is referred to as Documentation Center from here.

The Documentation Center has eighteen employees. A single person works with developing and maintaining the system in itself, three persons work with changes to
the documents (make sure that they are sound, get them approved, sometimes involving hearings) and twelve work with adding documents to the system. For instance by scanning, marking data and helping people to use the system. The people are traditional office workers.

The work is for a great deal related to adding documents to the system in the right way. The unit would like to be able to focus more on the content of the documents and in this way help make the shared documents be more useful but at present the time is swallowed up with managing, distributing and provide the documents with the right meta-data. The unit works with ideas as a more streamlined flow and the use of templates to reduce the workload associated with adding the documents.

The unit to some degree educates the authors in classifying and in how to write so that documents are more easily used. For instance a standardized method for writing is considered. A problem here is that many authors only write a few documents and that long periods pass where the persons do not write anything at all. Thus out of the about 2500 authors to the about 20,000 documents: almost 1600 have written 5 documents or less and almost 2000 have written 10 documents or less. About 75 have written more than 36 documents. An answer to this is to concentrate on the education of large “customers” such as secretaries.

Changes are made through the Documentation Center. A well-defined group make sure that changes are sound and major changes are controlled by another dedicated group.

**Documents**

20 approved documents and 40 in use in the new system. New system contains operational documents, the current rules, living vs. dead documents, documents with a life cycle, draft, current, dead.
Two main types of documents are found in the basic system: the operational documents found in the special subset contained in the superstructure and another groups of clinical studies and expert reports. In addition to this many other document types are found. The core customer is production but considerable amount is produced elsewhere. Mainly dealing with operation documents or documents central to the registration unit.

The information is stored in pdf format to achieve a stable layout of documents and to secure integrity. Some documents contain forms and to allow re-use of this type of documents the new system allow word versions of the forms to be downloaded. The original word versions can only be downloaded through the old system. The old system accepts all document formats. A great deal of thought is given to the choice of format in the Documentation Center. Central are here concerns of how perishable (durable) the documents are. It is to be expected that some format will last longer than other, due to new versions of interpreters or due to vendors going out of business. It is also of importance that a large amount of interpreters can be difficult to control. Finally it is problematic that some formats allow local circumstances at the reader heavily influence the presentation of the documents. Data may be presented in a way that leads to misreadings and errors which is of course not acceptable in relation to SOPs.

**Classification of material**

The material in the system is classified in various ways. A very important one is the classification of documents in relation to the distribution of the documents. A configurable push mechanism that allows people to find the documents they need.

The system is based on a four-layer classification scheme where a document is classified as top level, cross-functional, on departmental level or as item specific.

<table>
<thead>
<tr>
<th>top level</th>
<th>cross functional</th>
<th>departmental</th>
<th>item specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>what and by who</td>
<td>when, where and how</td>
<td>Instructions, equipment manuals, control of equipment</td>
<td>Directions for production, packing, analysis, etc.</td>
</tr>
<tr>
<td>Procedures</td>
<td>Procedures, forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>distribution profile</td>
<td>distribution profile, matrix number or two or more department numbers</td>
<td>department numbers</td>
<td>a number that unambiguously defines them, mainly product numbers or process numbers</td>
</tr>
</tbody>
</table>
Three ways to distribute documents: distribution profile, department number and item specific. Item specific uses an internal number to identify the document. Mainly a product number or an analysis number. The departments keep lists with overview of these numbers. These are often with access restrictions. They are mainly connected to a specific product or a production procedure.

The things that “pop up” at departments are called department lists.

The matrix number refers to an organizational area (e.g. production, early research, and resource management). They work on four levels with increasing specialization. Twenty-seven of these matrix numbers are used at present. Forty matrix numbers in four five are suggested for the updated system.

Using the categorization will also lead the person to think of who are the readers.

Forty-six document types are found in the new system. In all about forty document types are in use in the new system. These are specifications of one of the types in the original system (ISO documents). The original system has fifteen different document types. Each of the document types has an associated set of meta-data fields.

Some cross functional documents are treated like department specific documents since the distribution profile is not fine meshed enough. They then have several department numbers associated with them.

*Distribution profile*

The distribution profile is a set of attributes that makes it possible to decide where it applies. These attributes are determined and entered into the system as the SOP is added. Most low level documents are distributed through department numbers. Not all documents are provided with a distribution profile. The more general mechanism that is described next is not fine-meshed enough. The general documents are distributed through a set of attributes provided by filling in a form with 104 check boxes divided in four categories as shown below.
The square brackets show the fields to fill in.

In the table above some examples on the elements of each group are given. The “All” category are found in all of the groups. The form with the distribution profile also has fields for the document number in the system, the site and department where the document comes from as well as the name of the person responsible. It also has fields for the persons handling the SOP in DS where they can enter date, initials and sign for having handled the document.

The printed table of properties is sent in with the documents. Often as a suggestion for change, which must be approved by persons responsible for quality.

Between five hundred and six hundred documents are distributed through distribution profiles.

The distribution profile is not filled in for department specific documents. They are added to the collection as the other documents.

This arrangement makes it easy to add new departments. Once a profile is made for the department the right documents automatically appear. It is however difficult to add new classes and problems also occur when areas/departments merge. This could make it necessary to reclassify the old documents.

The systems are between two and three years old and no major changes have been made till now. A function/process was added to the distribution profile. This area is
harder to see through than for instance a site. It is more difficult to see where the documents “pop up”.

Creating classification schemes
The names can be given both by a drop down box and by writing the name. A misspelling will thus lead to a new category.

Sometimes the Documentation Center “clean up” the categories. The system is new but an estimate of the frequency is every year or every other year. New categories can be added by any person adding documents. This is however mainly done by Documentation Center personnel.

Sometimes these lists reflected the way that people were ordering their documents in the offices.

People wanted more document types. The categories were decided upon a central meetings where people presented which categories they needed. Very long lists were presented. The interviewed person was not involved in this work but think that it was done by first getting an overview of the existing categories and then boiling them down to a set small enough to manageable. It is estimated that seventy or eighty document types were proposed. A central issue here was that the larger the set of categories the larger the chance that people will not be able to categorize things consistently. The Documentation Center worked with an estimate that more than between seven and ten options will make it hard for the users to choose consistently. It is acknowledged that categories overlap and that exact categories can be difficult to define.

The attempts to reduce document types were also present before the introduction of the central systems.

“Everyone think that what they do is special.”

The classification scheme in the form is made by representatives from several departments. Various needs and perspectives led to a difficult decision process. For
instance it was discussed how many categories should be used. Some found it important to limit the number of categories to ease the use of the system, especially in the introduction period and for the users who rarely adds documents, whereas other meant that very elaborate schemes would be valuable tools for their work. Similar discussions were related to the allowed document types and their associated meta-data fields. All of the categories are controlled by the Documentation Center who are able to add and change the categories. This is done very rarely.

The document profile is then “filtered” through a set of department profiles so that the documents matching the department profile appears on the monitor when login onto the system with the name of the department as filter. The department filter is maintained by a dedicated administrator. Between one and three administrators are found at each site (23 sites, 30 to 40 administrators). Meant to have a site and a department administrator but is collapsed after a decision that one is enough. Most departments thus have an administrator but may have to take decision to the site administrator to get them approved. This person is responsible of ensuring that the department profile is up to date. In addition to this the administrator can remove specific documents from the set that appear even though it meets the requirements. This activity must be cleared with the person responsible for QA in the department.

Organizational origin
In this and the following section is it shown that the classifications are coupled to organizational structures and external standardization structures.

The documents in the system with distribution profiles are among other things related to the sites or units they belong to. Some problems have arisen with a recent de-merger in Novo Nordisk. Some units are split up, some are joined and some units now refer to other units than before. Some units even use the same name as before even though the functionality has changed. This makes it impossible to see who that refers to who. This situation has led the Documentation Center to consider the possibilities of categorizing the documents according to functions instead of to departments.

The de-merger brings with it a need to adjust the profiles of existing documents and of the departments to meet the new category structure. The way in which the problems
will be approached is not resolved as yet. Documentation Center are working on ways to adapt to the new organizational structure.

The impending changes are the first “real” update. The (20-25) administrators should be informed. The changes are proposed at hearings. It is then thought that the administrators should print a list of documents just before the change and hold it up to the list after the change and in that way adjust the profiles so that only the entire set of relevant documents are distributed to the departments.

It is still not clear how the potential reclassification of the documents should be done. It is at present not unrealistic to do it but it is a “tough job” and not made any easier by the necessary update of the paper version of the distribution profile lying with the document.

Standardization
ISO has a set of standards that apply for Novo Nordisk. These standards were used to create a document with entries for the types of documentation needed. This was then meshed with demands from Europe, America and Japan to form a table with types of documents (according to subject) and associated “ISO-subject numbers”. In all about hundred and twenty numbers are found. This list serves two purposes. First it is a checklist that all the relevant documentation is produced and secondly it is used to identify documents.

The people making the documents find the numbers themselves. They can ask Documentation Center for help. It is guessed that some of them have “homemade” solutions to the classification problem. For instance lists of often used ISO- subject numbers. Of course people can also refer to older classifications to see which number was assigned to similar documents.

The old documents were provided with ISO-subject numbers when they were scanned.

The ISO-subject numbers have been particularly difficult to “sell” to the document creators. “It is not always that easy to get numbers on the documents.”
A problem in relation to the ISO-subjects numbers is emerging. ISO is preparing a new set of standards and the question now is whether to use the new standard and thus change the system entirely, stick with the current one or make some compromise. A group is looking into the matter at present.

**Use of the systems**

Each month the system has 20,000 user sessions. A session is counted with every period of user activity. A session is kept alive as long as there is interaction with the system (with a timeout on 10 or 15 minutes) to avoid counting the same access more than once. Thus for instance pressing a button every 9 minutes for 8 hours will result in one session being counted. The number of session varies with workload, for instance it increases heavily in case of inspections where documents have to be made ready.

When using the system the list for a specific department is chosen. Usually the department a person belongs in, but it can be useful to choose other departments at times, for instance to see which documents they use in relation to a subject of common interest.

The users thus can by logging on the system immediately check if any changes have been made to current procedures and if any changes are impending. The documents are presented primarily sorted in relation to the level of applicability (top level, cross functional, department level and item specific level). The two first groups are ordered by ISO-subject number and then alphabetically by title. The documents on the departmental level are ordered by a numbering system locally controlled and specific for the department. This allows the departments to use already established numbering schemes in the central system. The item specific documents are ordered by their identity number. Another sorting key was considered but problems with fitting the design into a standard PC screen led to the current design.

It is possible to make other layouts by using the search functions in the system. Here the documents can be sorted by a range of attributes (e.g. department numbers, dates, document numbers). This function is however rarely used. Perhaps because it is not a
very visible in the system. It is considered to construct a set of “ready-made searches” that should fit typical requirements of specific users.

When a document has just been added an icon appear next to it showing that it is new. This stays there for two weeks. When a document is about to become obsolete or a document is about to replace an old one their status is signaled with icons. During the introduction of new versions of documents both documents are shown in a transition phase. Obsolete documents are deleted from the system.

In addition to that new documents appear in the new system an e-mail is sent once a week with the entire list of the cross functional and top level documents. This list is sent to people who want it, not to everybody. People are usually on terms with the department specific without a mail like this. In that way people can inform themselves about new documents also outside their profile. Locally the departments may have additional arrangements. Somewhere only a few people check the system and inform the other users that should be aware of changes. Some places one person is responsible and makes sure that current versions of the procedures are printed and kept in a shared binder.

The main beneficiary or the electronic systems are the people responsible for quality assurance. This function is spread throughout the organization and is typically part of the worktasks of an employee. With central, electronic systems it is a lot easier to introduce new procedure specification and to revoke old ones. In the old paper based days this could be very troublesome and involved many local binder archives.

The system is not necessarily very helpful in the normal work. Re-use could be done/is done anyway through shared local drives or through the individuals private copies. In the normal work the system can seem difficult to work with, inconvenient and unprofitable. It can be argued that the work of being ones own documentation center has been added.

Some places however the system is used to re-use data that would not have been re-used without a system of this type. During inspections people draw the information themselves in some cases they need to get the signed documents however.
Statistics from the use of the system are made public in monthly reports but no detailed analysis of the search or use is made.

It must be documented that a person has been trained within a certain area and thus that certain procedures are familiar to the person. A system is used in parallel to keep track of training. To some extent this could be integrated with the documentation system, however training is also required in non-document areas and as often a problem in the area it does also demand signature.

**Adding and changing material**

A user can/must add documents to the system according to procedures. For instance some of the documentation archived in the RMC in printed form must be added to the DS. The printed form in the RMC is added a reference number of the digital form in the DS.

The documents are added through an eight step process as described below.

1. The document is created, usually as a word document and e-mailed to the Documentation Center
2. It is converted to pdf in Documentation Center and e-mailed back to the author
3. The author prints and signs the file
4. The area of application of the document is determined by the author. A form is filled in and sent with the paper version of the document.

5. Documentation Center adds signature date to the pdf version.

6. Documentation Center adds the electronic pdf and word files to the old system by “capturing” them and adding the necessary indexation.

7. The printed version and the distribution profile scheme are archived in DS.

8. Correct distribution is verified by the Documentation Center.

The situation is described as a “wear both belt and braces”-solutions. As described above this brings some additional work with it if documents are to be re-classified.

**Classification issues**

A. distribution profile, department, item specific

B. properties, department numbers

C. stability of properties and department numbers

D. how are changes implemented/handled

E. how are the schemes originally created

F. the use of local archives
2 Working with CIS

In this chapter a series of observations of low level work with CIS is presented. The presentation is structured according to the units in which it took place. The work and the use of CIS and classification in laboratory units, legal units, research units and support units are described. In the next chapter a more integrating image in relation to the use of classification is drawn.

The figure below shows how the units that are described in the following are interrelated. The digital storage, DS and the material storage, RMC and their respective maintenance units, Documentation Center and RMC-unit, have been discussed above. The research unit, ResU, is where ideas for new product are produced. The laboratory unit, Immunochemistry, develops and uses methods to do test in development and production and the legal unit, Legal Discovery, handles information collection in relation to legal cases.

These are of course only a limited selection of the organization and will thus only present a part of the needs, strengths and weaknesses of the information structure. They do however present a large part of the types of work done in the organization and represent what can be described as producers as well as users of the shared document bases and of course the units that maintain the supporting systems.

2.1 Laboratory unit

Continuous testing and development of new testing methods are a necessary part of the work in Novo Nordisk. Here the work in one of these laboratory units is described.

Function

The unit produces and uses “assays”. These are methods to measure the occurrence of wanted substances and impurities in blood plasma. Methods to measure in occurrence
in water are used earlier in the development process of the substances and here the units cooperate across the phases in the project.

**The unit**

Twenty-nine persons work in Immunochemistry most of them are trained laboratory assistant (fifteen) or chemists (eight), a few office trained employees handle secretary and management affairs and two Ph.D. students do project work in the department.

People work in small teams with technicians and a chemist in each. The chemist writes the final report when the tests are through.

**Procedures**

Everything progresses in accordance with elaborate regulations. Every morning it is controlled if anything new is in the new DS, this takes a few seconds.

The person in charge of GLP (Good Laboratory Praxis) in the department knows the system well and is a convinced proponent of the systems. She tells that the work is very much easier with the electronic systems. Before this a troublesome procedure existing to secure that the locally applied procedures were up to date. It has however been a problem that people have been slow to start using the system. In relation to this it brought further inertia into the system that procedures had to follow ISO specifications before they could enter the new DS. The SOPs that were not yet in the system were kept locally in paper form in a shared binder placed in the hallway. These disappear slowly as they are updated since they new documents are in the system.

In the hallway a binder is kept where people sign for knowledge to or training in updates. This binder is for instance used in relation to the Danish health authorities, the health authorities from other countries (for instance America and Japan) and other controlling functions.

**Work**

The work is typically coupled to a project. A typical project runs over five to six years. Several “study plans” are coupled to a project, the number can vary widely
from around fifty to five hundred. To the work associated with projects comes
maintenance work internally in the department, for instance production of calibrators.

The tests are sometimes made by external chemical laboratories, foreign as well as
Danish. The results are sent to Immunochemistry but the laboratories keep their own
raw data.

A typical workday for a laboratory assistant is seven and a half hours in the laboratory
and half an hour with documents in the office. Once in a while however an entire day
is used on documents.

**Study plans**

Central in the work is the study plan. A study plan is a fixed and returning plan of
what to do and how to do it. It is made partly from standards of how work should be
done in general and partly from the planning made by the individual employee. For
instance often the substances to be tested are placed in measuring equipment
according to a plan made with the specifics of a single setup in mind and the
measuring process is the same for all the setups.

The work with a study plan can take from a day to two years. Several study plans are
used by the same employee at a time. The two employees that were asked both had
about fifteen plans at the time.

An example on a sequence:
1. Immunochemistry receives a description of a task (e.g. 30 rats, test them)
2. testing -> raw data
3. calculations and report
4. signed by superior
5. packed in envelope with label and describing documents
6. handed over to representative form RMC (who visits building twice a week)
7. receives receipt from RMC - these are places in a shared binder

Each study has a binder with a division of the material into eight categories:

- report
• study plan
• unforeseen events
• raw data
• used samples
• calibrators (documentation of locally produced and used substances)
• control (documentation of locally produced and used substances)
• correspondence

These are the documents that are collected and archived in relation to each study. The papers are kept collected in the binder until the are sent of with the report.

Archives
Several local archives exist. It is however important that the right documents are sent to the documentation centers and are not kept locally. This is specified in SOPs for the central archives. For instance material must be sent to the RMC before two weeks after the documents have been signed. The material that is currently worked on is kept in local fireproofed strongboxes.

The local archives are for instance used to re-use old study plans, tables and spreadsheets. This is either done by copying and pasting into the new documents or simply using the old document as a template for the new one. The old documents are ordered in a file hierarchy after their project number and the number of the study.

She also sees the system as helpful in that you can “steal” from other. However noting that it can be problematic to “steal” from other documents if you are not careful to make sure that the document is fitted to the local circumstances. For instance specifications and SOPs for equipment that are found in other units as well.

Packing documents
Making the documents ready for the archive is done according to a SOP and a sheet with a description follows the data. This sheet is made from filling in a word form. As described above five types of material exist.
• department related
• manufacturing related documentation
• good clinical practice
• good laboratory practice
• validation

The form is filled in with fixed data. That is the information is either straight forward or says so explicitly on the material that is packed (e.g. study number, the name of the person packing the data).

A description sheet exists for every study. Several studies can be put into one box. This can actually be requested by the Immunochemistry workers. A field on the description makes it possible to have an envelope placed in a box that has all ready been put in the RMC. In this way related studies can be placed in the same box and the number of half-empty boxes is minimized.

The study plan and the report are stored in the old DS when the report is finished. The DS (as described above) has a capture function that takes a word document as input and stores a corresponding pdf file in the central database. The document is assigned a DS number when added.

Thus some of the documents printed and stored in the RMC is also found in the DS. The number of the document in DS is added to the printed papers kept in RMC.

The figure below shows a simplified version of some of the relations between the laboratory unit and the material and digital storage. The figure shows the laboratory unit, the digital storage, the material storage and the placement and retrieval of SOPs, study reports, study plans, raw data and a description of the material.
Use of the stored data

The stored data is used, rather often and in very important tasks. Of central importance are the inspections by various institutions. When the health authorities visit the department they ask of things from the archives. Since the documents are in Immunochemistry sometimes only raw material are retrieved from the archives. The archives however do contain the original documents with signatures that may be required. For this use the system is highly effective. The system are also used between departments to re-use information (for instance part of study plans, equipment manuals or descriptions of equipment) or in general to see how people have previously done things. Other examples on use of the systems are found. Three are briefly mention here.

1. In relation to a development project an experiment was made where use patterns of existing systems were examined. To be able to do this it was necessary to get stored material from earlier work.

2. Another example is a guest from a foreign company who wanted to see examples on raw data to learn of the data manipulation tools in use (e.g. graph drawing).

3. A problem occurred once, when it after a while became clear that for some reason a batch of samples had not been recorded in the log of incoming material, even though the samples had been used and thus naturally had to have arrived. The problem was solved by retrieving a logbook of the centrifuge from the RMC. All samples of this type have to be centrifuged the same day. From this log it was clear that the material had arrived and this backtracking argument was used to document the arrival of the samples.

The material in the digital storage is located in various ways according to the situation at hand. It can be accessed by:

- knowledge of a colleague (initials) and a project number
- a local laboratory procedure number (which will only give a few documents)
- a project number (which will give many documents)

The use of the old digital storage system is mentioned in relation to this. It makes it possible to construct the registration file (use in approvals of products) by searching on all documents related to a project (hundred of thousands of documents) and then filtering the irrelevant documents. This is also of use in relation to patent lawsuits.
The system is used in parallel with the private file structure and the printed versions in binders (used when longer passages are to be read, to avoid reading from the screen).

As could be expected the way that DS is used vary between individuals. The interviewed person is familiar with the system and has a special interest in the system as being responsible of GLP. It would thus not be surprising if she because of this familiarity with the system is more comfortable with using it and more inclined to do so than people who use the system less often.

At times she is contacted by persons wanting information from studies (that is not the entire description but part of the information in the document. The entire document may be used as well - this is unclear. The use that other persons make of the documents accessible through the DS is unclear to the author - not statistics are made available.). This is interesting in that it points to the access to documents (or maybe rather information related to the documents) is often mediated through persons (either knowledge of the person (e.g. search on initials) or through asking). The interviewed person is more inclined to search the system than to contact the creators. (This may be the case for other persons as well, it is not clear because of the lack of statistics on use of the documents. The use not based on personal contact may be larger or smaller than the use revealed by contacts.) She to some degree associates her inclination towards using the system with her placement in the hierarchy. As a laboratory assistant you do not just phone a person higher up in the hierarchy. This is more obvious to do the other way round.

On being asked she stressed that on requests she either gives the wanted information (not document but part of it) or gives a path for the document in old DS - not a copy of the digital document on the personal PC. It is important because of the special role assigned to the “original”.

**Classification**

As could be expected a wealth of classifications is used in the laboratory. Their relation to CIS is discussed in the next chapter. Here an overview of the most interesting classifications is provided.
It is possible to see the office as a place between the laboratory, its samples and equipment and the shared information bases where the worked up results and corresponding documentation are found.

**Laboratory**

- Objects and labels
  - Results and data
  - Logs of materials

**Office**

- Reports
  - SOPs

**Shared centers**

In the production of the results from the studies a range of information is used locally. For instance logbook of received samples and procedures for use of laboratory equipment.

**Field of work**

The field of work itself is dominated by classifications. This is expressed through:

- placement of substances and samples in various closets, with corresponding safety regulations and temperatures
- labeling of substances, samples and all sorts of equipment with printed (sometimes filled in by hand) paper labels
- types of areas, for instance laboratories, offices, cold stores, meeting rooms with associated rules for clothing, hand washing and the likes
- papers being classified in relation to several schemes. This is discussed elaborately below

**Departments**

Classification of departments and their function is necessary for the distribution of SOPs as discussed in above. With this of course follows a classification of SOPs to match this classification.

**Employees**

The employees have roles (e.g. chemist, laboratory assistant and secretary) and in addition employees are certified to various activities. For instance training and test is required before one is allowed to work with each specific type of studies.
Work
The work is divided into smaller parts often related to either overall projects or maintenance. Documents, data and work are thus classified in relation to the overall project or task they relate to.

Parts of work
Within a project a set of sub-studies may exist, each with a study number and within each study the work is split into various activities of which some has clearly marked beginnings and conclusions. The work can also be seen as classified in relation to the elaborate regulations.

Documents
Several types of documents are found and each of these is classified in relation to a range of aspects. Some prominent examples are:
- the person they belong to (the responsible person, the person keeping them, the person writing in them etc.)
- in relation to project (for instance in the shape of a file structure on a workstation)
- personal/private vs. shared/public
- printed vs. digital (maybe even online)
- official vs. work paper
- in operation, soon to be in operation and obsolete
- study plan, deviations, raw data, calibration, etc. (the order in the study binders).
  This classification is based on an OECD guideline for GLP. It is rarely changed (estimated maybe every five years) and then mainly changes within the classes used here
- the closets in which they belong (sort of reverse classification, they probably belong in the closets because they are of a certain class, or ?)
- own documents vs. documents from the outside

A department specific SOP is found for adding department level SOPs, this is specifically minded on the requirements and the type of documents found in the department.

The common chemical understanding and understanding of the field of work is important for the use of documents. Documents should be self-contained, that it
should be possible to read them without any knowledge that is not either basic for working in the area or documented in documents referred to in the document.

**An example on the work**

The work that at any time is carried out is mostly part of a larger project. A useful way of splitting up the work is in relation to studies. This distinction is also used by the people working. A study plan is associated with each study and every study is concluded with a report, these are kept in the RMC with the corresponding raw data, calibrator documentation etc. (data from the measurements in the laboratory) and in DS (study plan and report only).

The department has a series of ongoing projects with associated studies. The studies are divided among the employees in the department with consideration for the current capacity and expertise. They are allocated to a team of chemists and laboratory assistants. Within this team it is planned how the study should be distributed in time. A whiteboard with the numbers of the studies, the responsible person and dates is a tool in the studied team. This is placed in the office of the chemist, who acts as leader.

The studies are allocated to the teams by head of the department, who keeps a database with an overview of projects, responsible teams, deadlines etc. This database is accessible to the employees in the department. The team leaders are able to update some of the fields in the database. This is called a master schedule and is used as a tool to make rational allocations of work, to maintain overview and to predict workload.

A study is associated with a project (with a project number) that runs across the organization. It is used from early development (how this is done and how early is unclear) and through the various phases. Thus every study has a project number that is shared throughout the organization. This overview is not used to locate documents. A subset is however used to predict workload. The intranet includes the possibility to see the list of active project numbers and their status (e.g. where are they in the process, where are they going next).
A study has a study number as well. This is however not shared throughout the organization and the way that the number is chosen is not a simple one. The study number is either done according to quality standards and then has a number assigned by a quality department or is not done according to quality standards and has a number assigned according to the local arrangements of the department. In the studied department it is attempted to use the quality standards also for studies that do not require this. This is to avoid working with more than one set of standards, which is seen to be potentially confusing and may lead to problems with making people adhere to the quality standards in the situations where it is required.

When a number is assigned by quality departments a distinction is made between whether the Immunochemistry is assigned the study as part of the overall project plan or if they are asked to do tests by a department who are assigned to do a study as part of an overall project plan. In the first case the department is study director and the study has a number assigned by the quality department. In the second case the department is principal investigator and the study is associated with a number from the department that acts as study director, the study is also assigned a number from the local quality department. Several quality departments exist. For instance one for clinical, one for pre-clinical and one for manufacturing. The quality departments thus have master schedules of the studies and their associated numbers this is not used in finding material. The overview is not accessible directly but could be accessed through contact with an employee there. Even though in principle this provides numbers of the studies this is not used to locate documents. “Instead the old digital storage system is used. It is much quicker to find things this way.” The quality department master schedule is only interesting to see if work is impending.

As mentioned each of these studies has an associated study plan, which is a specification of how the study should be carried out. This study plan is made accessible to other groups and departments in the organization when the study is archived. As many of the studies are similar it is possible to re-use parts from previous plans. This re-use may be across teams and across departments.

An elaboration of the study plan is made by the laboratory assistant. This is a very specific description of the study. It has fields wherein the results from the laboratory
can be written down and where the setup of the experimental equipment and the specific activities (e.g. exact quantities of substances to be used to make a solution) is planned previous to the start of the work in the laboratory. It is described as the study plan being a specification along the lines of:

- you are to produce this
- from this
- using these as standards

The elaboration contains setup schemes and work documents with the exact way in which to fulfill the demands in the study plan. “It is a way in which to live up to what is written in the study plan.” Re-use of part of these low-level plans from previous experiments is also possible. This re-use is also done within the team but not across teams or departments.

During the work in the laboratory copies of the study plan and the low-level plan and setup are used. The “recipe” for the experiment is continuously consulted to be sure of the procedure - even if the experiment has been done before. The scheme of the setup is used to make a correct setup and to note the results and potential deviations as they emerge.

In addition to the computer and handwritten results from the study prints from various laboratory equipment are used. For instance both a computer coupled to a chromatograph with software for data manipulation and an electronic weight produce prints of test results that are part of the raw data.

Some of these data are entered in spreadsheets in the computer in the office where further calculation are made. In the observed case these among other things were used to show if the tested material were within the specified limiting values of the test.

The summarizing scheme is printed and a control is made where the person having made the experiment sits down with a colleague and assures identity between the data and the summarizing document. This is done with the technician reading the results from the prints and notes from the experiment and the colleague checking that the values are transferred correctly. During this a lot of marks and notes are made in the
documents. These partly serve as evidence that the values are correct and partly serve as pointers to values that are to be corrected. When the document has been gone over the technician goes back to the spreadsheet and makes the necessary corrections from the marks and comments the colleague made in the print. This elaborate description allows a comment on the nature of ephemeral/working information. Here is an example on shared ephemeral information and how the information changes status, from shared to not shared and from ephemeral to archived information.

The study plan, the setup scheme, the data from the experiment, the summarizing document, a scheme where unforeseen event are specified and documentation of control and calibrator are placed in a binder. The last two are produced and approved by quality department once every half year and used in several studies and are kept in the fireproof cabinet.

Documents are continuously transferred to the study-binder, as they become relevant and are during the experiments kept on tables and ordered in relation to current tasks with transparent plastic folders.

The chemist writes a report of the study and this and all the papers are gathered, packed and sent to the material archive. At the same time the study plan and the report is added to the digital archive in the old system. The documents are added to the digital storage first to allow the identification number in the digital storage (DS ID) to be added (by hand) to the originals (the printed and signed documents) that are sent to the RMC. This set of categories of documents is the same for the studies and thus makes it easy for people to use binders, even if they are made by a colleague.

Most often several experiments/tests are running in parallel in a way so that activities that belong to more than one experiment must be continuously coordinated to a degree where shifts are made with five minutes doing one thing and five minutes doing something else. This in partly due to the nature of the tests where substances undergo stirring, warming, and electronic measuring processes in intervals that range from thirty seconds to four hours or more. This makes it necessary to shift between overall tasks to get a rational arrangement of the separate work tasks.
The figure below provides an overview of a selected set of documents used in the process described above. Only a subset is included, the omitted documents are for instance the log of received materials and the labels on equipment, substances and samples. The aim with the figure is to illustrate the multifarious representations of information that is involved in this rather simple task.

Figure text. The figure provides an overview of the most important document types and their relations. Grey boxes are digital documents, white boxes are paper-based. Frames means that the documents are found in the system associated with the frame. Arrows indicate that the document itself or information or structure from the document is transferred into the next representation. Cylinders denote digital storage media, e.g. computers or databases.

It is not possible to read any time flow from the figure.

**Shared structures**

In relation to the above-described sequence alone, at least four areas with shared documents are found.

- digital storage
• material storage
• locally shared files on the computer network
• Calibrator and control documentation

To this can be added:
• shared logbooks of received materials
• documents with descriptions of equipment, safety regulations and chemical substances placed around the work place
• the last paper based SOPs
• individually owned and maintained copies of articles, books and old reports which are used by other workers. This can either be done through the owner who acts as a librarian (aware of existence, locates, lends) or if the owner is away (meeting, called in sick, vacation) it can be done by the person needing the material locating the documents using knowledge of the structure of the archives of this individuals, presumable obtained at least partly through previous loans and other observed uses of the archives by the owner. The private archives to some degree are thus also used as shared archives.

Use of documents
In this study it was (once again) confirmed that physical documents play many roles, of which storing information is only one. They are used to point to, afford easy transport, can be used as evidence (especially when no clear legislation in the digital signature area exists), sort worktasks, be used as note paper, allow an efficient control process. In addition some remarks on the dynamic role of documents can be made from the use of spreadsheets and calculation programs where ideas are tested and useful shapes of representations are figured out.

DS is used for operational documents. The cross-functional level and top level documents are mainly created in departments further up the management hierarchy. Proposals for documents can have an origin in the Immunochemistry. This type of documents usually go through a series of hearings on their way from draft to final version. However a lot of department level SOP are found. These are made in the Immunochemistry and approved by the quality department. All of the SOPs are
revised at least every third year. Department specific templates are created to help create new SOPs. The SOPs can be divided into four types:

- **general** (e.g. how is a SOP made, how is binders maintained, how is substances ordered - “everything that is not practical”)
- **guidelines** (much like general SOPs only not a “binding”)
- **laboratory procedures** (practical procedures related to laboratory work, can be specifically related to a project)
- **equipment related** (descriptions of technical equipment and manuals)

The procedures may be general as well as very specific and often relate to each other.

<table>
<thead>
<tr>
<th>general</th>
<th>guidelines</th>
<th>laboratory</th>
<th>equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>44</td>
<td>5</td>
<td>81</td>
<td>55</td>
</tr>
</tbody>
</table>

Number of department level SOPs in Immunochemistry.

**Stray ideas**

Knowledge of the stock of samples was used (specific types of monkey and dog plasma) and exchange of samples was negotiated to meet the demands of the various groups in the unit. That is, the stock situation was sorted out by informal communication and samples were used jointly in the department. This is also the case between departments. For instance several e-mail inquiries about various samples were received in the department. People were to some degree aware of the needs in other departments and were aiming to help them.

Ph.D. students and master students are doing projects with the department on and off. The students are supported with knowledge and equipment by Immunochemistry. In relation to this the DS and various individual archives are used to find documents that are connected to the students research areas. For instance it was necessary to use the digital storage to find full versions of some incomplete paper copies of a document and to look in the logs to decide the specific nature of a set of samples given to a student by a person who was on vacation.

It is interesting to note the special demands put on documentation and the function of formal constructs here, including the two functions of documents (external and internal use). A few thoughts on the role of plans as they are discussed in “Plans and situated action” are obvious. When I read the book the first time a helpful mental image of the discussion was the image of a cook following a recipe. A good cook
would know if the pepper he was using was especially strong, if the eggs were small, which spices could be swapped etc. A written recipe in a cookbook is a perfect example on one aspect of the situated nature of action. My old chemistry teachers used to say that chemists were good cooks because they knew how to follow a recipe. So this study should be a perfect example on master cooks and their use of their “recipes” in their work in the laboratories.

2.2 Legal unit
The legal unit of Novo Nordisk consists of several subdivisions with specific functions. For instance separate units are dedicated to security in the workplace, contracts with external partners and trademark issues. A unit here called “Legal Unit”, Legal Discovery, was studied. Legal Discovery is responsible for providing the attorneys with internal documents for use in American lawsuits.

History
The unit was established in ninety-seven. The function is a result of an increased presence on the American market, where the number of documents considered of importance in relation to a lawsuit is much larger than in Europe. This difference can be in the order of between four thousand and twenty thousand documents in a British case against between one hundred thousand and four hundred thousand documents in an American. Until the start of American lawsuits not need was found for a unit with the single function of procuring documents.

Function
The lawsuits are run by an external firm of lawyers who are familiar with the local legislation. The firm works with Novo Nordisk through a group especially set up to follow lawsuits. The role of Legal Discovery is to provide the lawyers with the document the need.

The litigation team contains jurists, people from the patent unit, the leader of the American unit and people working with the organizational strategy. This current team has been effective for at least two years.
The collaboration between the law firm and Legal Discovery happen through e-mail, telephone conferences and an occasional face to face meeting in relation to the attorneys visiting Denmark to interview central persons. During the process additional demands for documentation can appear and new rounds of collection can start. Several law firms are used. For instance to avoid that the law firm is connected with the suing party.

In principle three month (or maybe is it thirty days) are provided to obtain the information but this parameter is often extended to six month and follow-up questions can lead to even longer periods. This depends on the case as well as the judge. This deadline is important since failing to put forward the requested documents can lead to loosing the case or if Novo Nordisk is the suing part that the case is dismissed. Since the documents are to be found, read, potentially translated, transferred, read by the attorneys and have determined a degree of confidentiality this is rather short time. Legal Discovery is thus continuously monitoring potential lawsuits and preparing for impending lawsuits before the document request. This time pressure lead to a large change in the number of employees. A case typically takes five to six years if it goes to court and a couple of year in case of settlement.

At receipt of the papers the law firm stamps the documents with a number demanded for use in American lawsuits. The legal process in itself is not discussed here. It is however interesting to note that the documentation is investigated in relation to confidentiality in Legal Discovery as well as by the lawyers to make sure that the material is handled with correct access rights. Documents that are typically not readily shared are for instance production methods, marketing plans, strategies and minutes from board meetings. The confidentiality level is determined by Legal Discovery (to the degree that time allows) and the by attorneys.

Some of the Danish documents are translated for Novo Nordisk’s attorneys. For instance laboratory books are often kept in Danish. The documents are handed over to the other side as they are, that is sometimes in Danish.
It is at times difficult to transfer American concept to Danish concepts, when in doubt the matters are discussed with the American lawyers.

It is also central that all requested documents are put forth. If it is revealed that relevant documents are not handed over it can mean loosing the case. This for instance can be revealed during examinations of employees from Novo Nordisk. Thus it is very important that all documents are found.

**Legal Unit**

At present three jurists are employed in Legal Discovery, of which one is trained within the American legal system and has personal experience from working in America. Within the last two years the number of employees has varied between three and six. The need varies with the number of cases in progress.

For instance copying documents at times demands extra help. It is interesting to briefly consider this job. The job mainly consists in copying documents and packing them in boxes and thus requires no formal training. However it is important for an effective handling of the procurement of documents that the employees continuously monitor, register and reflect on the work (In Danish “følger med i arbejdet”) and thus get an overview of the material that has been provided and of how pieces of documentation are related. And it is important that the employees see their function in the wider context. This allows easy reacquisition and acquisition of related documents. This in combination with the temporary nature of the job leads to a situation where mostly students taking a break in education (for instance while saving for travels), who are actually “overqualified” for this type of work, are employed. The use of students actually led to the construction of the current database system, which was made by a student with IT skills, while he was employed to copy documents. This is interesting in that it:

1. shows the importance of social structures not directly connected to education (at least if this is seen as a tool of transferring task or area specific application oriented knowledge and methods) in relation to creating structures that constructively form the work done in organizations
2. shows that this type of job involves more than the functions specified in the contract and task-design and that the additional job content is difficult to specify (getting an overview, work with a feeling for the wider context)

3. it shows how some systems are created on the run; come to existence somewhat by chance and may grow larger as they are found useful (Legal Discovery is currently working with ideas of sharing the information in the database with other units)

**Documents and documentation**

In Legal Discovery a distinction between documentation and documents is stressed. Documents are paper, electronic documents, video and the likes, that is “the physical the company has got” (in Danish “...det fysiske virksomheden har.”). Whereas documentation is related to the content of the documents or the information they contain, the things that Legal Discovery has to find are not interpreted. Of course the content must be analyzed to some degree to determine whether a document is of relevance to the case, but this is related to the subject or context of the document only. During the classification of documents into classes with different access restrictions Legal Discovery moves a bit closer to the content, but the documents are still not considered documentation. Legal Discovery at times has been searching for documentation as well. When producing documentation the concern is to document a process this leads to another way of searching for evidence.

**Procuring documents**

As stated earlier many different types of documents are used. For instance minutes, notes, internal letters, e-mails, reports, promotion material. E-mails and other digital representations are printed before they are packed similarly to the material found in binders. The documents come from all parts of the process. For instance the start of development, applications for various approvals, tests, production planning, production, marketing and sales. Papers are retrieved from fifteen or twenty people to fifty or sixty people, some time up to a hundred people, varying strongly between cases.

*Determining the relevant set of documents*

An employee describes the documents of interest as follows: “We do not know what we are after. Someone has got to tell us what we are looking for.” The method for
getting document has been designed somewhat by trial and error and is continuously improved.

Central to the document procurement is a “document request”. This is a list of documents from the attorneys. In case of Novo Nordisk being sued this list is made by the suing party. The documents are described in various ways ranging from very specific descriptions to general characteristics (e.g. organizational charts, production methods, results from research and test, expected payoffs, anything related to knowledge of a specific subject). The list is the result of a negotiation between the attorneys of the two sides. Since it is costly to provide and go through documents both sides may have an interest in limiting the number.

The document request is handed over to the litigation team who finds the persons who have been in contact with the product or patent, often project leaders and persons with patent rights. The people in the litigation team know which products Novo Nordisk has and has an overview of the organization. It is not clear how this overview is constructed and maintained.

A document request contains several items or groups. The number may vary widely, two examples had respectively thirty and a little more than a hundred points on the list. Documents may be added to the document request as new questions arise. They can come from the other side as well as Novo Nordisk’s own attorneys.

From the document request and the list of persons Legal Discovery works their way through the relevant persons and documents by inquiry. The persons are asked which documents they have and what persons they think may have relevant documents. In general talking to people is a great way to get overview of the documents and a
central mean for document procurement. Then documents are “borrowed”, copied in two copies of which one is archived in the unit and the other is sent to the lawyers and the originals are returned to the owners. Legal Discovery also find persons that the attorneys can interview to get information of the case.

The document request thus serves to find the relevant area (product, patent, phase in project) and through this persons who may have documents or know other persons who may have documents. The list also serves to determine if the documents that are found at these people are relevant. When contacting people about documents the wording of the document request is used and people consider the relevance of their documents according to this.

**Working transversely to the organization**

It can be difficult to work across the organizational hierarchy to get information. It can involve “teasing” information out, or contact with superior personnel.

It is preferred that the documents are not found through the normal chain of command. That is, it is an important and conscious choice not to establish contact with the people having the documents through their superiors. Partly because this is bothersome and will slow down the process. But more importantly because it is undesirable that the information is debated openly and that people gets an overview of the business of which they knew nothing before the case. It is important that people tell the truth, as they know, it in the trial.

Departments change over time, so it is important to find the people who dealt with the case of interest. The product distinctions are used, but numbers are not given by the start of the search process. They come into use by the people who are asked about documents. The organizational charts are not of much use. At least not the charts of any given present since the import chart would be the charts of the time of the production of the documents.

**Finding documents at the keepers**

People never have problems with interpreting the document request and most often easily located the needed documents. These are kept in shelves in the office, the hallways, basements and on floppy discs or hard discs.
If the original keepers of the documents are no longer to be found a manager associated with the function is contacted. At times looking for the documents somewhat resembles detective work.

Most of the material is ordered in binders by the people who keep it. The ordered is retained and the copied material is provided with labels that tell which binder it came from (the text on the side of the binder), the name of the person that kept it and the name of the person who owns the document. The paper is packed in boxes containing each two thousand sheets. Documents belonging to each binder are separated by a piece of paper marked with what the cover of the binder said and the two related persons. The box is marked with an index of the binders in the bow. As the boxes are continuously sent no total overview of the packet material is sent.

It is important for Legal Discovery that people do not feel disturbed and annoyed by their work. They aim to be flexible and work from the principle that people have other jobs and that the Legal Discovery sort of intrudes on this. They also take great care to make sure that the documents are delivered in the same condition, order and “wrapping” as the were “borrowed” in.

In Legal Discovery a database containing a list over all of the collected material is kept. This could be imagined used as evidence (even though this has not been necessary yet) and is a tool for providing overview.

In relation to classification it is interesting to note that: a) The type of document is not of any importance in the procurement process. Anything can be important, depending on the type of case. A travel report that showed to contain central information is an example on this. b) The document type is not really considered in relation to the determination of confidentiality level either.

Strategies for obtaining documentation

The documents that people work with are rightfully per standard considered confidential. “It is a healthy instinct to deny access.”
Work is made a lot easier when the Legal Discovery employee knows people from earlier. It is necessary to establish familiarity and confidence to the function. Legal Discovery thus works with strategies for approaching people and for introducing themselves. No best solution however does exist. People are different and require different methods. Some like a formal letter first, to ensure that the procedures are respected, whereas this type of letter (especially coupled with a lawsuit) makes other people uncomfortable and may lead to defensive hostility or people ignoring the enquiry. This is one of the many reasons for non-replies. People are “paralyzed”, they do not know how to handle the situation and then simply do nothing. These people are better approaches by showing up in person, explaining the situation and the way that people can help. In Legal Discovery it is assumed that this is coupled to showing that Legal Discovery are normal people and that they are on the same side as the people with the document. That they are actually working together. Here showing flexibility is also a very useful tool for making people cooperate.

No distinction is made between different types of materials in the collection process. One might have expected relevance of characteristics related to content of documents or placement in relation to the material, structural surroundings (e.g. approved procedures, e-mails or handwritten notes). This type of classification is of no importance in the document collection. Things are simply retrieved in the same way no matter what kind of documentation it is.

Another interesting classification is however used. Various departments have different cultures, which strongly influences the best strategy for getting documents. For instance a distinction is often found between marketing people and researchers. It is not easier to get documents from scientists but the means for doing it are different.

<table>
<thead>
<tr>
<th>Marketing</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• highly restrictive with document access</td>
<td>• less restrictive with document access</td>
</tr>
<tr>
<td>• committed to authorities</td>
<td>• independent and potentially stubborn</td>
</tr>
<tr>
<td>• are convinced through superiors</td>
<td>• are convinced by a reasonable case</td>
</tr>
<tr>
<td>• are quick to follow orders</td>
<td>• will argue against decisions from superiors</td>
</tr>
<tr>
<td></td>
<td>if they find them problematic</td>
</tr>
</tbody>
</table>

Thus strategies for dealing with (types of) people are found rather than strategies for dealing with types of documents.
Use of archives

In the overall legal unit several other archives are used. For instance paper based archives of contracts, correspondence and earlier cases. The unit working with security in work has a special system designed for their work. Here local archives and the use of the two central archives are examined.

Legal Discovery considers using RMC for their material but till now the material is stored locally in boxes just as the material that has been sent. The material is not necessarily destroyed after a case is closed but may be kept with a view to potential similar cases. It is imagined that it will be considered continuously which things can be removed from the storage. For instance a case in another country or another attack on a patent can lead to similar cases. This means that the process in finding documents is still the same in that persons should still be asked if they have relevant material, but it is not necessary to “borrow” the documents from the offices to copy them.

DS and RMC do not take up much time in the work of the Legal Discovery employees. Only a few out of every thousand documents are acquired by use of these systems. For instance procedures can be retrieved from DS. The systems are not seen as central sources of documents they are on the contrary almost invisible. It should be noted that this is considering documents only - not information. The documents found in the system may and may not be central to a case.

A range of reasons is found for the central archives not being sufficient to meet the demands of Legal Discovery. The procurement process may be made somewhat easier by having all documents in electronic form and this may be strengthened if they are kept centrally, but these two things in themselves do far from solve the problems that Legal Discovery face.

Not knowing what documents are needed

The employees in Legal Discovery as a rule do not know what documents they are looking for. A few operating procedures and other central documents may be known. Mainly however they know the type of interesting documents but not which documents that mach these criteria. It is seen as an advantage that as many people as
possible think the situation over. In that way it is more likely that all of the relevant documents are found.

The interviewed person considers if a list of the clinical studies could be used to point out the interesting persons instead of as now the opposite situation where people are asked which studies that exist. First of all it is not clear if such a list exists. Secondly an important perspective is that: “[y]ou have to contact all the related person anyway, so you might as well do it from the start.” When Legal Discovery is visiting people to talk about relevant documents it is a lot easier to simply get the documents when they are there, than to get them from the central archives later. This comes naturally when talking to people about which documents that are relevant. They mostly have the documents themselves and they do not refer to the storage (this has happened less than five times).

Here it should be noted that most cases demand recent documents. It is expected that a product liability case will lead to stronger use of RMC, because these cases go further back in time and thus may require documents that are not kept in the local archives but can only be found in RMC. This has until now not been relevant.

*Needing all versions of documents*

All versions of a document must be obtained. If an employee has made a couple of marks or written something in a printed version this has to go into the documentation pool. All versions of the material is needed, not just one “original copy”. “In principle we empty out company.”

*Some material is not kept in archives*

Some of the information they do not have in the storage. The RMC do not contain certain types of information (e.g. minutes, laboratory reports, documents saved on computers, floppy discs, e-mails, little handwritten notes).

*Transversal to the archive structures*

It is difficult to search the archives from the information on the list. The search functions do not match the concepts that Legal Discovery has of the documents. Legal Discovery so to speak “approach the documents in the organization from another angle”. It is not possible to search the content of the boxes specifically enough. It is stated that Legal Discovery has a somewhat different perspective than most of Novo
Nordisk in relation to the storage functions. (In Danish “[Legal Discovery] er lidt skæv i forhold til [lagerfunktionerne]”. “We are not considered users and the use from our side is minimal”.

**Getting an overview**

For the work of the Legal Discovery it is central to be able to get an impression of the associated documents. This is possible in the local archives where the documents usually are kept with similar documents. To some degree this may be met by the way that related documents in different envelopes are sometimes placed in the same box in RMC.

**Documents can not be marked sufficiently**

The search criteria do not match the needs in Legal Discovery. It is probably impossible to mark all data in relation to the potential later searches. For instance in early research it is not known which product the research will relate to. And the product may be the key with which the Legal Discovery has to identify relevant documents.

**Bothersome procurement procedures**

In addition it is bothersome to get documents from the RMC. It requires permission from the owner of the document and that the exact document is identified. It should be noted that the limited use of the RMC is not the result of cooperative problems. In fact the RMC is known for fast and efficient service.