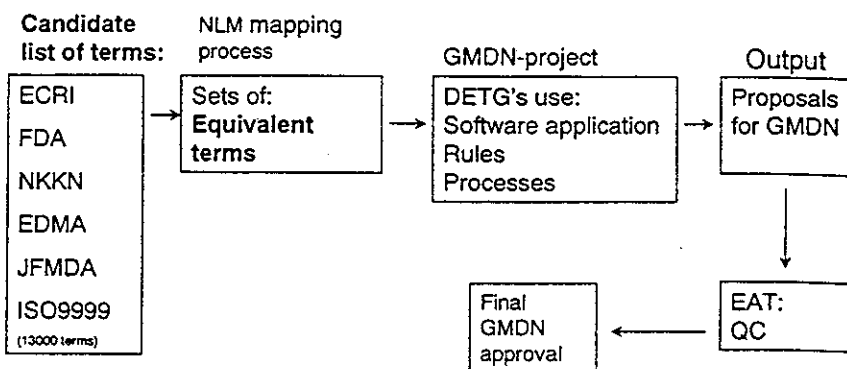


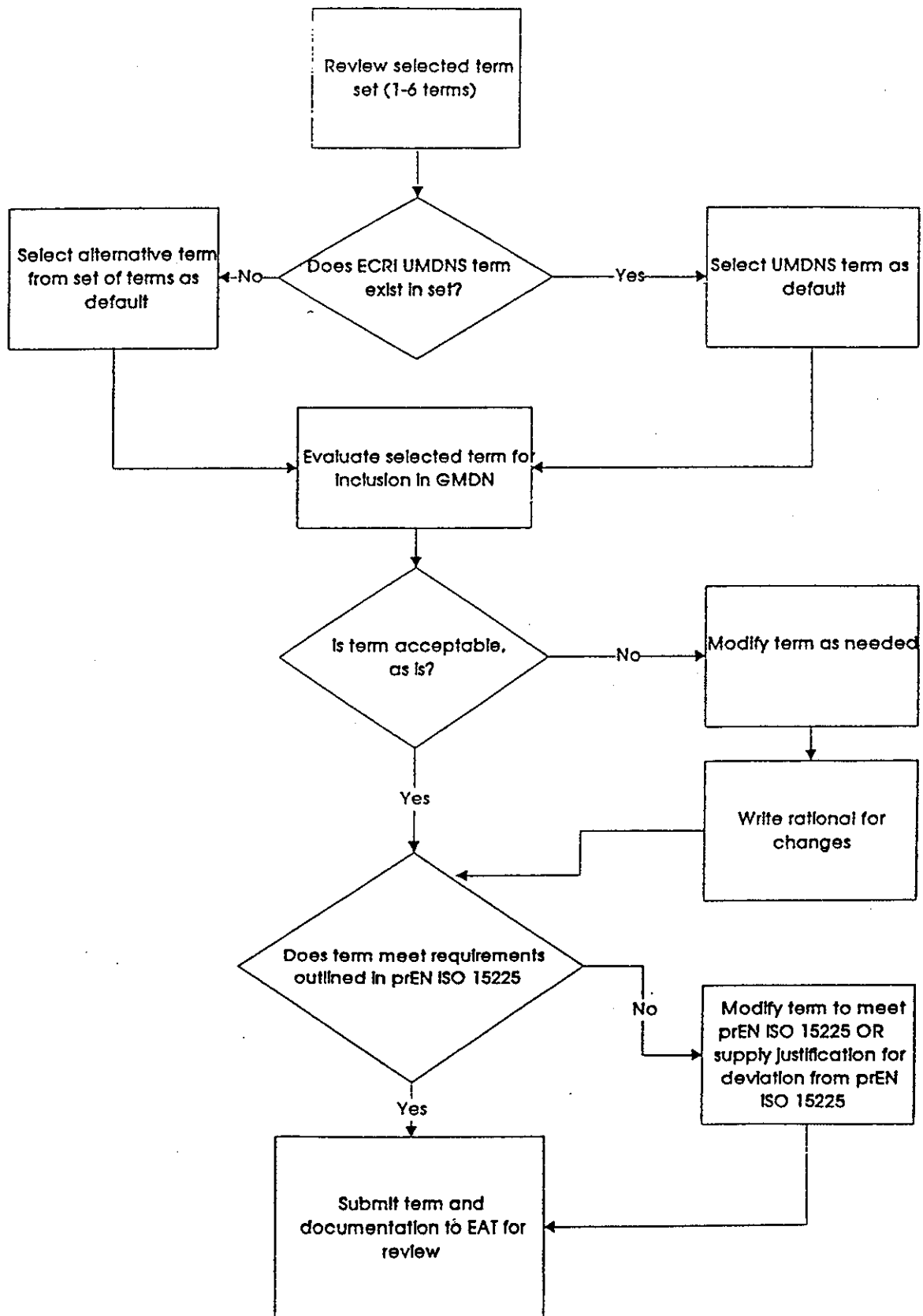
Process for generating the GMDN



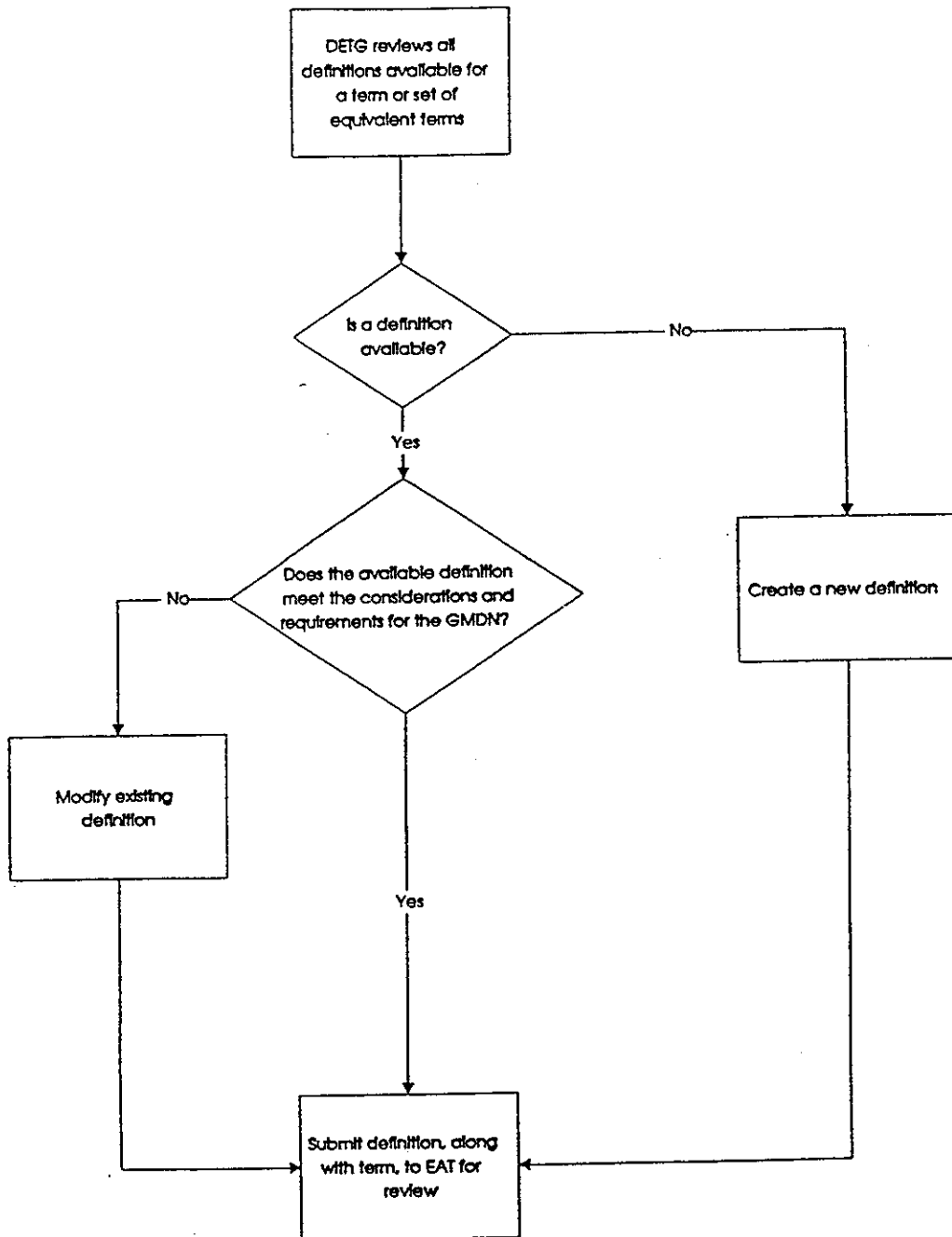
August, 98

Definitions & explanations

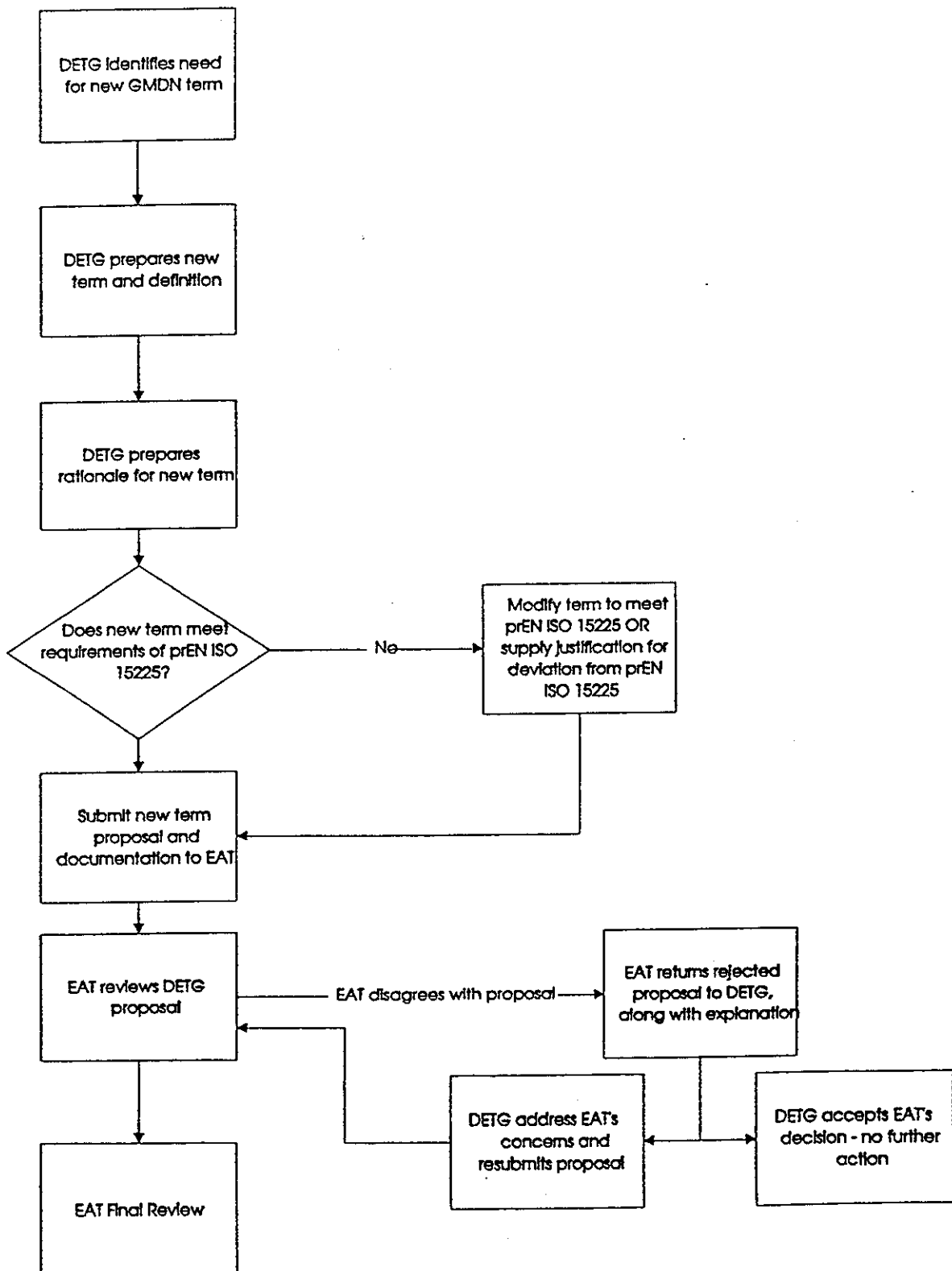
3



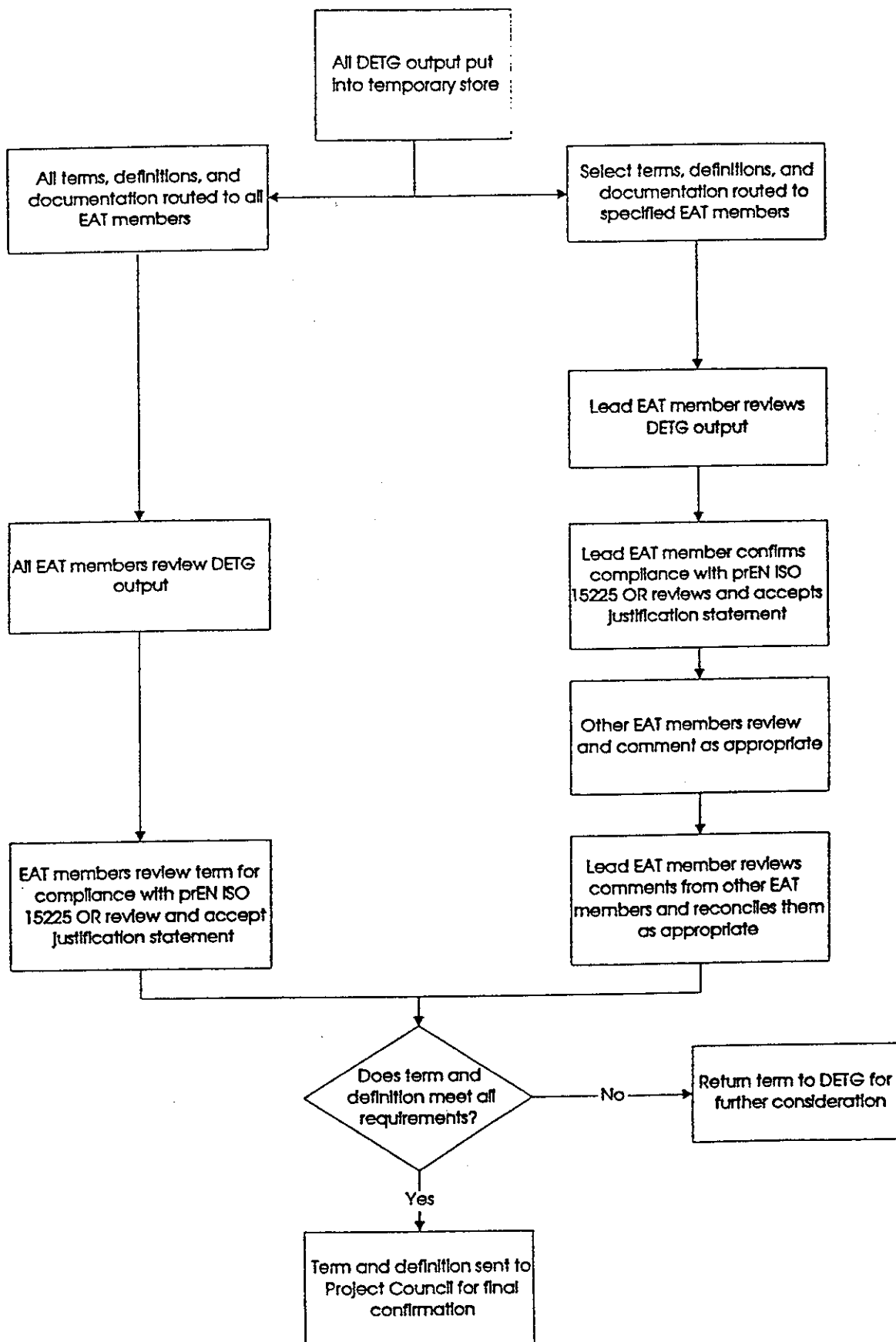
Flowchart - Reviewing/Creating Definitions



Flowchart - Suggesting New Terms



Flowchart - EAT Review



GMDN IT Training Manual

Section 6.1

Introduction

Unipart Information Technology
May 1998

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6.1.1 GMDN IT Training Manual - Contents

This manual will be made available both as a paper document and as a Lotus Notes database. As a Notes database, the table of contents will be provided automatically as the Notes "view". The contents are summarised here for those reading a paper copy.

Section 6.1 Introduction

Notes Training

Section 6.2 Getting Started
Section 6.3 Notes Mail
Section 6.4 Discussion Databases
Section 6.5 Referring to Other Information
Section 6.6 Replication
Section 6.7 Using the GMDN Application

Installing Notes and Setting Up you Network Connection

Section 7 Installation

Section 7.1 Overview
Section 7.2 Modems
Section 7.3 Installing Trumpet Winsock
Section 7.4 Installing Dial-Up Networking
Section 7.5 Installing Lotus Notes
Section 7.6 Copying Notes Databases from CD
Section 7.7 Infonet Dial-up Telephone Numbers
Section 7.8 Infonet Dial-up Telephone Numbers (USA)
Section 7.9 Installation Help Desk
Section 7.10 Sample User Information Sheet
Section 7.11 Problem Avoidance and Resolution

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6.1.2 Lotus Notes and the GMDN

Unipart Information Technology were approached in the summer of 1997 and invited to submit a proposal for the development of an IT system to support the development of the Global Medical Devices Nomenclature. This project would involve a large number of people, spread over several countries, working together to reach agreement on the words and phrases that could be used to describe medical devices, that would be unambiguous and acceptable to all. Unipart recommended that Lotus Notes should be used for this. Why?

Characteristics of the GMDN application

- The users are widely dispersed, and will be working in isolation from each other
- The information to be handled is entirely in the form of text
- The process of defining and agreeing a term must be traceable
- A vehicle is required for discussion and gaining consensus

Characteristics of Lotus Notes

- It is a system that allows people to access centralised data as if it were local, without being permanently connected to the central system.
 - It is a system that focuses largely on text and other "non-formatted" data - that is, data that doesn't always fit neatly into rows and columns.
 - It is a system that allows applications to be developed and changed quickly and easily.
 - It runs with Windows and is easy to use.
 - It provides a number of other facilities such as electronic mail (email) and discussion databases or forums.
-

6.1.3 What is Lotus Notes?

This is a very difficult question to answer, but fundamentally, it is a system to help people to work together, no matter where they may be.

Databases

Notes is a system that maintains databases of information. Any kind of information can be held in a Notes database - text, numbers, pictures, sounds, or even movie clips!

Servers

A server is a large computer which can store a vast amount of data for a large number of people. A server is where the "master" copies of a database reside, although with Notes there can be several servers each holding a "master" copy. Notes uses a process called "replication" to keep all of those copies synchronised.

Clients

A Notes server might support hundreds of "clients". A Notes client is the piece of Notes that works on your PC. It too can hold its own copies of databases, and replicate these with a server. Notes clients cannot communicate directly with other clients, only through a server. Notes clients generally run on computers with Microsoft Windows, although they can also run on other computers such as Apple Macintoshes.

Electronic Mail

Lotus Notes allows you to send mail to other Notes users, and receive mail from them.

Communication

When Notes has been setup properly on your PC, communication will be automatic - you just tell the computer to start communicating, and it will make the connection through an ordinary telephone line, send and receive mail, replicate databases, and disconnect again. You do not have to be connected to the server to do your normal work, you can simply replicate daily, weekly, or at whatever interval suits you.

Notes will dial a telephone number in your own country, so you will not be faced with large telephone bills. We are using a Network called Infonet which handles the communication from your local country to the Notes server which is based at Unipart in Oxford.

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6.1.4 Unipart Information Technology

Unipart Information Technology (UiT) is the Information Technology division of the Unipart Group of Companies.

The Unipart Group of Companies

Unipart started life as the Parts division of British Leyland, now the Rover Group. In 1987, it was the subject of an employee buy-out. Since then it has grown and diversified and is now a leading player in the move towards "the company of the future"; as such, it has taken on and European-ised a number of Japanese working patterns and practices, such as "Kaizen", or continuous improvement, and "lean" working techniques.

Unipart now consists of a number of divisions, the major ones being:-

DCM - or Demand Chain Management - Providing logistical services for Rover, Jaguar, Hewlett Packard, and a number of other companies

UI - or Unipart International - Distributors of Unipart's own brand of automotive components

Unipart Industries - Manufacturers of a number of automotive components, including exhaust pipes, petrol tanks, and air conditioning units.

Complete Communications - A marketing and communications company

UniqueAir - Selling cellular telephone air time

UiT

In addition, a number of new ventures in the railway and health industries, and joint ventures with other automotive companies such as Honda, have been instigated in the past couple of years.

Unipart Information Technology

As the information technology arm of the Group, UiT runs the logistical and financial systems that run the company from day to day. UiT has extensive experience in mainframe systems, client-server computing, PCs, and networks. Hundreds of Unipart's customers and suppliers all over the world have computer links to Unipart for services such as parts ordering and EDI.

In 1992, Unipart adopted Lotus Notes as a means of sharing information and supporting Unipart's business initiatives. This was a great success, and very soon more than 1500 employees and a number of external parties were connected.

Based on this success, UiT formed an External Sales group to sell Notes-based services outside the Group. This team quickly became accredited as Lotus Business Partners, and then Lotus Premium Partners. Several members of the group have been trained alongside Lotus's own consultants and are accredited to work alongside Lotus Consulting on Lotus's key projects.

6.1.5 The GMDN Application

The GMDN application has been written by Unipart to meet the GMDN project's requirements, as specified by the Expert Advisory Team (EAT).

It takes as its starting point a list of candidate terms, and provides a number of facilities for the DETGs, including the ability:-

- select terms for processing,
- amend terms
- approve terms

The system also allows for terms to be approved or referred back by the EAT.

The application is based on Lotus Notes, and makes use of Lotus Notes's replication facilities to allow each user to operate on his or her own copy of the database and to communicate changes with the central "master" database copy.

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GMDN IT Training Manual

Section 6.7

GMDN Application

Unipart Information Technology
May 1998

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6.7.1 Glossary of Terms

Throughout the following documentation various phrases and words will be used. Below are the definitions :

Workspace

The name given to the working area within Lotus Notes. The workspace is divided into a number of user-controlled folder tabs. Within each tabbed section there are a number of databases loaded represented by squares. To open a database the user needs to double-click with the left mouse button.

Navigator

Navigators provide the user with a graphical way to find documents or process actions without having to maneuver through views or find menu commands, in so doing enhancing the user-friendly interface.

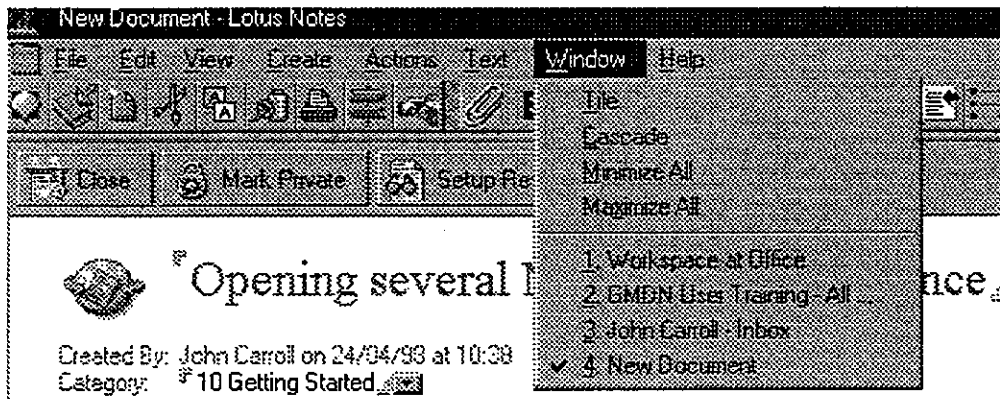
Action Buttons

Action buttons are a means of providing common functionality in a single button. Within most systems there are processes which require several key presses or mouse clicks. Action buttons replace the need for this and provide similar functionality in a single click.

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6.2.5 Opening several Notes Windows at once

You can have up to eight Notes Windows open at the same time. For example, if you open a database, and then open a document within it, you will have three windows open, and you can swap between them using the "Window" menu item at the top of the screen. If you click on "Window" you will see something like this:-



As you can see, there are currently four open windows, and you can move between them with the mouse. If, for example, you select "Workspace at Office" here, you will be able to open another database, while the existing Windows remain open.

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6.7.2 Operating Environment

The GMDN System has been developed to provide an extremely user-friendly front-end with a powerful back-end. After double-clicking on the GMDN database from the Lotus Notes Workspace the user will be presented with the Main Menu Navigator (see below). The navigator is the "front door" into the system and every area in the application can be accessed from this point.

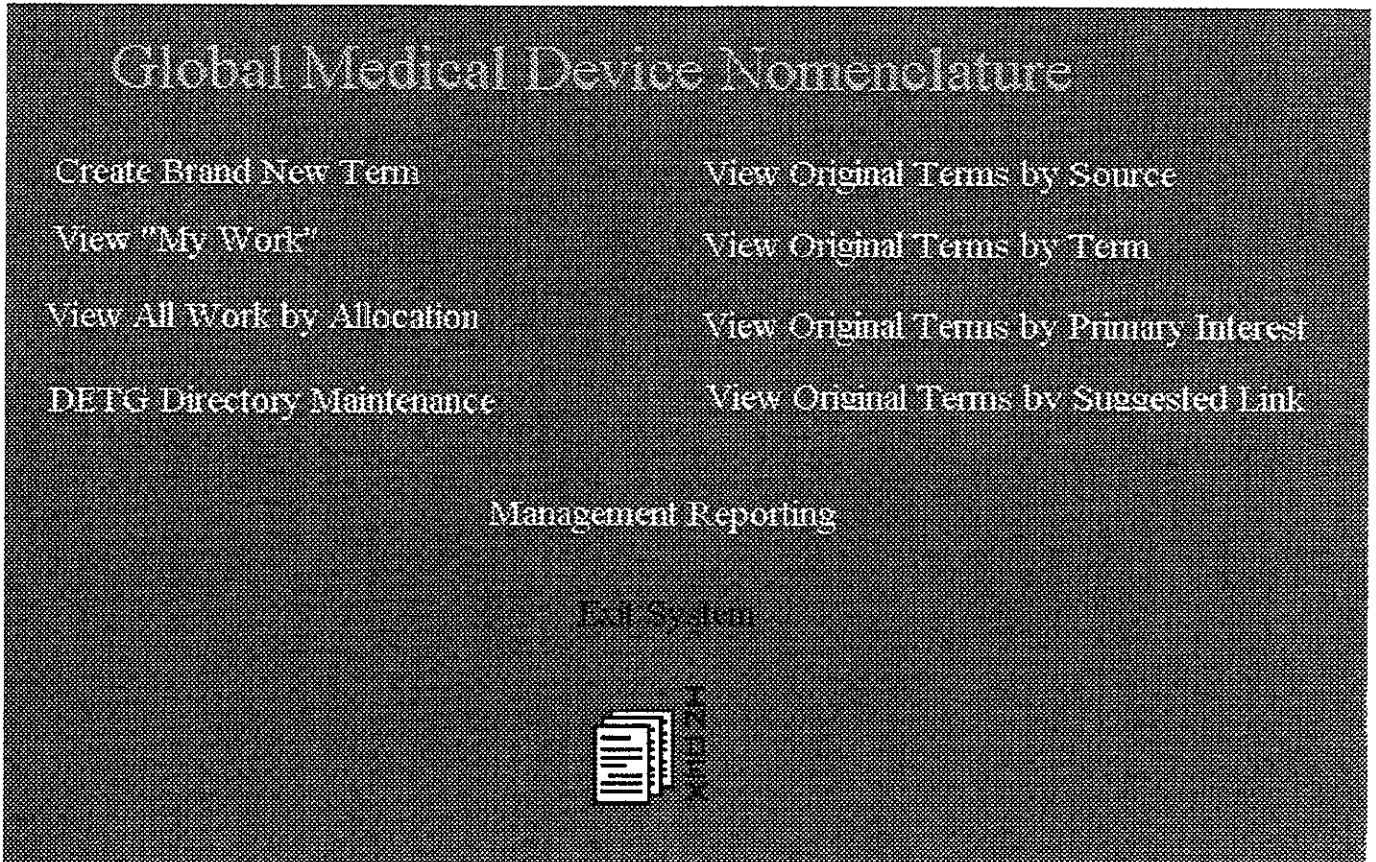


Figure 1 - Main Menu Navigator

Using the "Main Menu" Navigator

1. Move your cursor over the option/area you would like until a red, hotpot outline appears.
2. Single click with your left mouse button - the screen will either show you a blank "GMDN Entry" form (if you chose 'Create Brand New Term') or it will show the chosen view along with either the "Views" navigator or the "Reporting" navigator (see below).

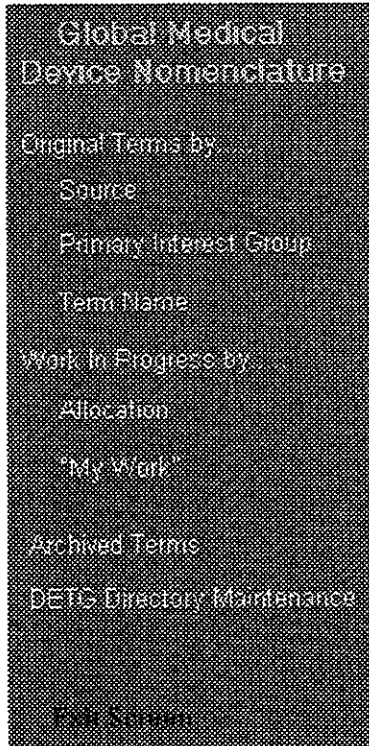


Figure 2 - Views Navigator

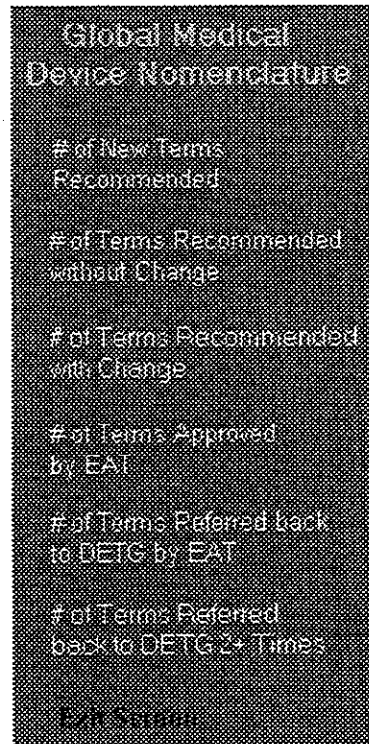


Figure 3 - Reporting Navigator

These navigators work in exactly the same way as the Main Menu except you cannot create a New Term from them. It is used to change the way in which the user is looking at the individual Terms.



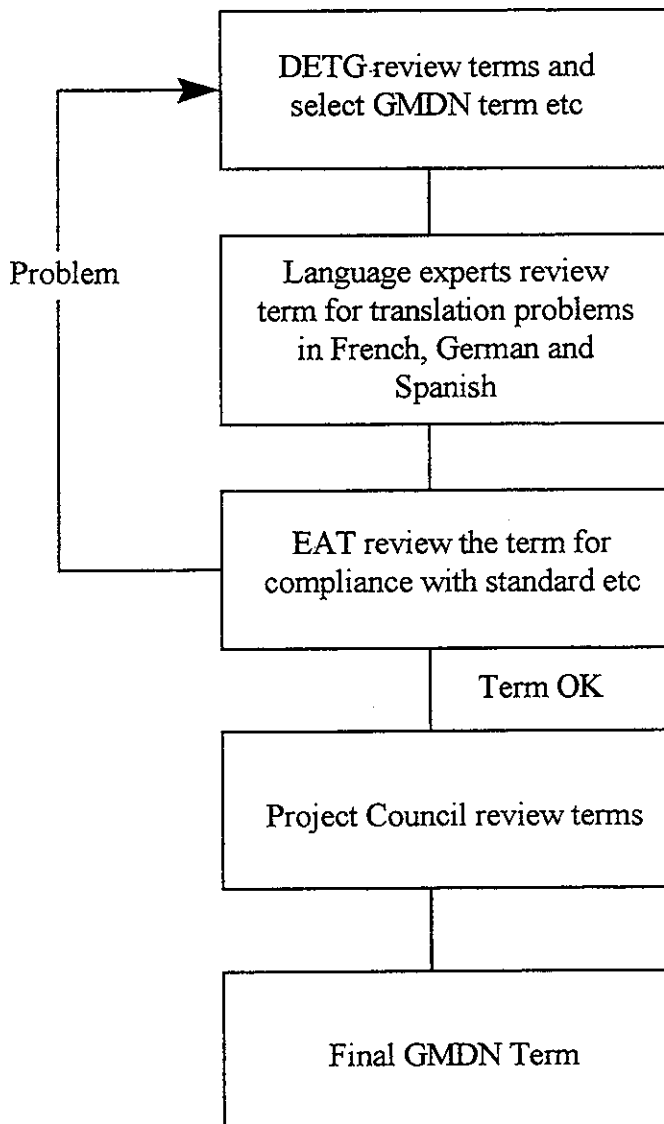
Figure 4 - Action Buttons

Figure 4 shows Action Buttons. These buttons will be found at the top of forms and views within the system. The buttons are a key feature of the GMDN system in that they are used to create the hierarchy between Terms. In general, action buttons allow users to complete often lengthy tasks at a single click of a button.

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6.7.3 Documented System Process


Below is a flow chart that outlines the Process around which the system has been developed.



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6.7.4 DETG Members User Guide

The following outlines the functions and responsibilities that the DETG Convenor and members undertake when using the system.

Upon first entering the system you should choose to look at the Original Terms by Primary Interest Group. This will open the database and you will see every term that has been assigned to your DETG. Review the list to see if there are any obvious mistakes in the allocation. If there are then the Convenor needs to Reallocate the term to another DETG (see "Convenors User Guide" ).

Once you are happy with your list it is time to get to work. Change to the "Original Terms by Term Name" view using the navigator on the left hand side of the screen. Within your particular DETG you must decide together which terms you must concentrate on - for example, you may decide to look at alarms. Using the Search Bar (pictured below) search for Alarms by typing in Alarm and hitting Search.

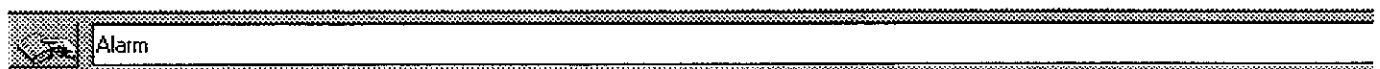



Figure 1 - Search Bar

After this has completed you will be presented with a list of terms on the screen all associated with Alarms. Simply select which terms you wish to work on by clicking in the left margin of the view with the mouse whilst also checking the details on the screen to make sure that you are supposed to be working on the appropriate terms.

	Original Term	Source	Primary Interest	Allocated
✓	ALARM, GAS CENTRAL SYSTEM	NKKN	DETG1	
✓	ALARM, PRESSURE/FLOW	NKKN	DETG1	
✓	ALARM, PRESSURE AIRWAY	NKKN	DETG1	
✓	ALARM, GAS	NKKN	DETG1	
✓	ALARM, FLUID LEVEL	NKKN	DETG1	
✓	ALARM, EPILEPSY	NKKN	DETG1	
✓	ALARM, ENURESIS	NKKN	DETG1	
✓	ALARM, APNOEA	NKKN	DETG1	
	ANAESTHESIA, ANTI-HYPOXIA UNIT	NKKN	DETG1	
✓	ALARM, HYPOPNEA	NKKN	DETG1	
✓	ALARM, <SPECIFY>	NKKN	DETG1	
✓	ALARM, CONDITIONED RESPONSE ENURESIS	FDA	DETG1	
✓	ALARM, PILLOW PRESSURE	FDA	DETG1	
✓	ALARM, LEAKAGE CURRENT, PORTABLE	FDA	DETG1	
✓	ALARM, BLOOD-PRESSURE	FDA	DETG1	
✓	ALARM SYSTEMS	ISO9999	DETG1	

Figure 2 - Selecting the Terms

Now that the terms have been selected you need to allocate them to yourself. This is done by using the

"Identify Work in Progress" action button . You will be presented with the allocation dialog box and you need to select your name from the list and hit OK.

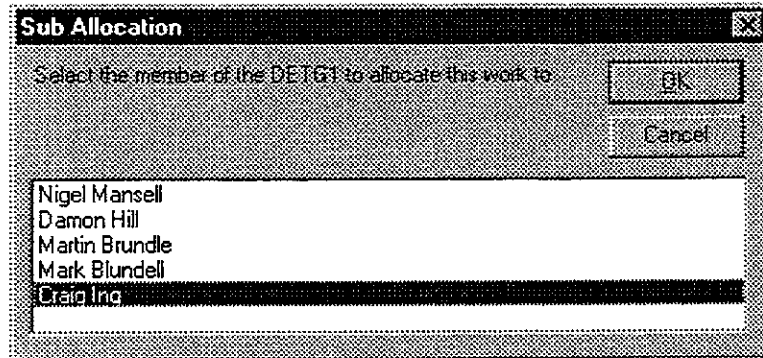


Figure 3 - Allocation Dialog Box

The terms you selected will now have moved into the "My Work" view and now you can start to create hierarchies and suggest term names etc.

Figure 4 shows the GMDN Entry form. This is the form that contains all the information relating to the term, it's definition, it's code, it's source and also all the approvals and comments made throughout the recommendation process.

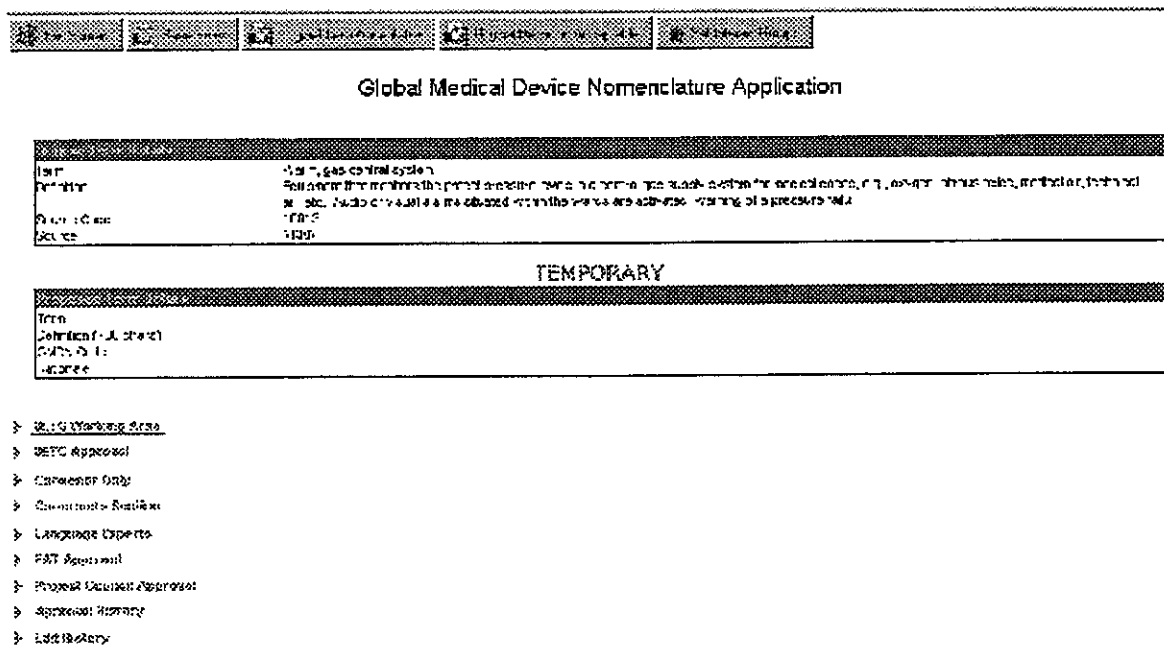




Figure 4 - GMDN Entry Form

As part of the allocation process, you are given control of DETG Working #1. This is where you will do all your work relating to the term. From here you can create a new term name, new definition and then give your rationale for your decision as well as record ad hoc comments.

To change the term details expand the DETG Working Area section by clicking on the arrow next to the title and then click the "Update Proposed Details" button . This will present a dialog box in which you can change the appropriate details.

Once you are happy with your Generic Term you can click the "Exit Screen" button and select "Yes" when asked to save changes. You are now ready to create the hierarchy between Preferred Terms, Equivalent and Synonyms.

Remembering which term was your Preferred Term highlight it and click the "Identify Preferred Term" action button . This will mark your Generic Term as preferred. Now you must select it's equivalents and synonyms using the appropriate action buttons. Once you have completed this for one set

of terms you will be faced with a view looking something like Figure 5.

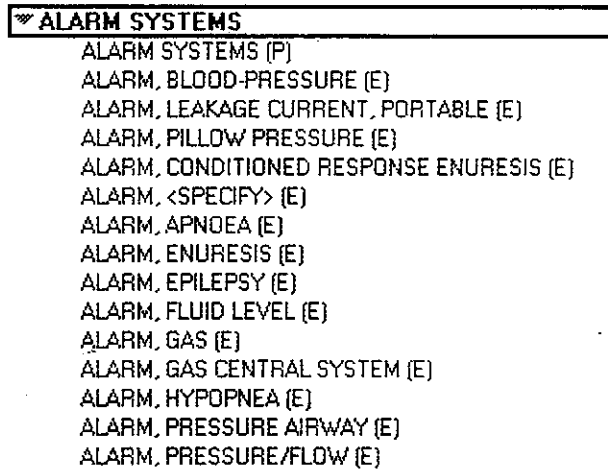


Figure 5 - Hierarchy for a Generic Term

Now that you have completed a Generic Set you must transfer it back to the main group so the Convenor can assess it and if all is well pass it to the Language Experts for review. To do this select the Preferred ONLY and click the "Pass to Main Group" action button. If you do not do this correctly you will get an error message. After clicking the button the system will select all related terms and allocate them back to the Main Group ready for the Convenor.

You are now ready to start on your next set.

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